

An updated User
Survey
Of
LadyBalance[®]
Vaginal Tablets

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Contents

Update of user survey	3
Collection of Data	3
The Use of LadyBalance.....	3
Effects of LadyBalance	5
Effect on Discharge with a Fishy Smell	Fejl! Bogmærke er ikke defineret.
Effect on Discharge with a Neutral Smell	Fejl! Bogmærke er ikke defineret.
Effect on Itching and Smarting	Fejl! Bogmærke er ikke defineret.
Dryness	Fejl! Bogmærke er ikke defineret.
Lack of Sexual Desire.....	Fejl! Bogmærke er ikke defineret.
Lack of Sexual Endurance.....	Fejl! Bogmærke er ikke defineret.
Side-Effects of LadyBalance	10
LadyBalance and pregnancy	16
Perception amongst persons allergic to milk.....	17
Effect of change in production method	Fejl! Bogmærke er ikke defineret.
Conclusion	Fejl! Bogmærke er ikke defineret.

Update of user survey

The present report is an update of former reports done in 2009 and 2013. The questions related to different periods of use have been simplified, and information related to use during pregnancy are included..

Collection of Data

This study is based on data from an electronic questionnaire amongst 956 customers of LadyBalance.

On 10th October 2017 an e-mail was sent to all customers who had purchased LadyBalance vaginal tablets in the Internet shop in the last 3 years. The e-mail included an invitation to participate in a survey and a link to a web-based questionnaire. Moreover, the recipients were informed that when they returned the questionnaire they would automatically have the chance of winning a gift voucher to the value of DKK 1000 to a local restaurant. Reminders with links were forwarded to the users who had not answered the questionnaire 27th October and 9th November. The questionnaire was sent to 3148 customers all of whom had given their e-mail addresses when they purchased LadyBalance. Out of these 956 had completed the whole questionnaire or parts of it. 95 abstained from participating and 53 e-mail addresses were not accepted. Disregarding the addresses that were not in use the overall response was 31 per cent, slightly lower than the last questionnaire. This is considered satisfactory since such questionnaires often get caught in the spam filters. There is no bias towards users who have a usable e-mail address.

The LadyBalance Users

The questionnaire covered special medical situations, where the use of lactose vaginal tablets may have an influence. The number of respondents with these specific conditions is listed.

Table 1. Number of participants with special situations covered by the questionnaire (Number and percentage of those replying on this question)

	Number	Percentage
Recurrent cystitis (bladder infection)	214	24
Seeking conception	69	10
Cervical lesions	83	11

The Use of LadyBalance

Out of the 956 responses, 899 (94 percent) had used LadyBalance vaginal tablets. The 6 per cent non-users would be persons that purchased for others. The questionnaire did not allow forwarding of the link to the user.

As shown in Table 2, 29 per cent of the users have been using LadyBalance vaginal tablets less than one month, 28 per cent of the users have been using the tablets in 1-3 years. Twenty percent has used the tablets for 3-12 months and for more than 3 years.

Table 2. The time period where the used has been using LadyBalance vaginal tablets (Number and percentage for each time span)

	Number	Percentage
Less than one month	242	29
3-12 months	169	20
1-3 years	235	28
More than 3 years	164	20
Do not know	26	3

N= 836 users

As shown in table 3 the majority used **one** tablet daily in the periods where they use LadyBalance vaginal tablets. Some users use even less than ½ tablet which will require them to cut or break the tablet.

Table 3. When using LB. how many tablets per day the users typically apply (Number and percentage)

	Number	Percentage
More than 1 tablet	17	2,0
1 tablet	545	65,2
½ tablet	220	26,3
Less than ½ tablet	49	5,9
Do not know	5	0,6

N= 836

As shown in Table 4 the majority of users (32,1%) used 2½ - 5 tablets per month, 25,6 per cent used two tablets or less per month while only 17,4 per cent used more than 10 tablets per month. The figures mentioned can be recalculated to state an average consumption of LadyBalance tablets of 6,3 per month.

Table 4. Number of LadyBalance tablets per month the users apply (Number and percentage)

	Number	Percentage
½ - 2 tablets	214	25,6
2½ - 5 tablets	268	32,1
5½ - 10 tablets	165	19,7
10½ - 20 tablets	99	11,8
20½ - 30 tablets	45	5,4
More than 30 tablets	2	0,2
Do not know	43	5,1

N= 836

Table 5 shows the problems the users of LadyBalance wished to cure. It shows that the majority (83 per cent.) of customers have purchased LadyBalance for the purpose of reducing the problem of a fishy smelling discharge. Thirty five per cent have bought the product to improve problems related to itching or a smarting sensation. 11 per cent wished to reduce problems relating to a neutral smelling discharge and 19 per cent wished to improve their problems with dryness. Moreover, 3 per cent wanted to improve their lack of sexual desire and 1 per cent wished to improve their sexual endurance.

Table 5. Users' problems and reasons for purchasing LadyBalance (Number and percentage)

	Number	Percentage
Discharge with a fishy smell	681	82,7
Discharge with a neutral smell	90	10,9
Itching/Smarting	286	34,7
Dryness	156	18,9
Lack of sexual desire	24	2,9
Lack of sexual endurance	11	1,3
Recurrent cystitis	50	6,1
Failing conception	4	0,5
Prevent virus infections(HIV,HPV a.o.)	12	1,5
Remedy cervical lesions	11	1,3
Others	53	6,4

N=824

Note: The users can select more than one answer and the percentages must not add up to 100.

Effects of LadyBalance

This chapter describes how the customers experience the effects of LadyBalance after using it for one week, one month or a year.

The effects are calculated only for customers that have described having the particular problem. Since last survey an applicator has become available. The users were requested to reply with the perception when using the applicator, if they have used applicator. Specific questions cover the effect of using the applicator.

Effect on Vaginal disorders after use for one week

Among the users who have replied the questionnaire, 785 have used the product more than one week. The perceived effect of using LadyBalance vaginal tablets for one week is shown in table 6.

Table 6 shows that among users who seek an improvement to discharge with a fishy smell 61 per cent have experienced a 'much less' degree of the fishy smell already after a week's use of LadyBalance. 32 per cent have experienced 'less' smell. Totally, 93 per cent of the users facing problems related to the fishy smell experienced a reduction in the fishy smelling discharge after using LadyBalance for a week.. 0,3 per cent of users with the actual problem has experienced 'more' fishy smell while none has experienced 'much more' fishy smell.

There are 370 users who have problems with discharge with a neutral smell. Among these users 21 per cent experienced that the amount of discharge was 'much less' after using

LadyBalance for a week. 34 per cent experienced that it was 'less' while 22 per cent did not experience any difference; 9 per cent experienced 'more' and 3 per cent experienced 'much more' discharge with a neutral smell. Thus, a total of 55 per cent of the users with the problem have experienced an improvement. However, there are a few users who have experienced 'more' discharge with a neutral smell. This is included in the description of the side-effects described for the product.

There are 402 users who have problems with itching or smarting in the vaginal area. Among these users 38 per cent experienced that the problem became 'much less' after using the product for one week and 46 per cent experienced that it became 'less'. Thus, 84 per cent of the users experienced that problems with itching or smarting decrease after using LadyBalance for one week. Ten per cent of the users with the problem experienced 'no difference' while 1 per cent experienced that the problem became 'more' or 'much more' intense.

For the 305 users who used LadyBalance to combat dryness, 45 per cent experienced that the problem occurred 'less' and 25 per cent 'much less' after using LadyBalance for one week. 1 per cent of all users had experienced that their problems with dryness had become 'more' or 'much more' prominent after one week's use. Thus, a large part (70%) of the users experienced an improvement in their problems related to dryness after using LadyBalance for one week.

Among the 191 users who indicated the lack of sexual desire as a relevant problem, approximately 20 per cent experienced that the problem was 'less' or 'much less', while the 50 per cent did not notice any difference. 'Do not know' was answered by 28 per cent.

Among the 175 users who indicated lack of sexual endurance as a reason for using LadyBalance, approximately 20 per cent experienced that the problem was 'less' or 'much less', while the 47 per cent did not notice any difference. 'Do not know' was answered by 31 per cent.

Table 6. Effect experienced on the specified problems indicated after one week of use. The percentage is calculated for the users indicating having this particular problem.

Effect experienced	Much less	Less	No difference	More	Much more	Do not know	Total per cent	Total number
Discharge with fishy smell (BV)	60,9	32,3	4,8	0,3	0	1,7	100	691
Discharge with a neutral Smell	21,3	33,8	21,6	9,2	2,7	11,4	100	370
Itching and smarting (yeast)	37,8	46,3	10,0	0,5	0,3	5,2	100	402
Dryness (Atrophi)	24,6	45,3	20,3	0,3	0,3	9,2	100	305
Lack of sexual desire	8,4	12,0	50,3	0,5	0,5	28,3	100	191
Lack of sexual endurance	7,4	12,0	47,4	1,7	0,6	30,9	100	175

N=785

Effect on Vaginal disorders after use for one month

Among the users who have replied the questionnaire, 442 have used the product more than one month. The effects are calculated only for customers that have described the particular problem as relevant.

The perceived effect of using LadyBalance vaginal tablets for one month is shown in table 7.

Table 7 shows that among users who seek an improvement to this problem 63 per cent have experienced a 'much less' degree of the fishy smell already after a month's use of LadyBalance. 28 per cent have experienced 'less' smell. Totally, 91 per cent of the users facing problems related to the fishy smell experienced a reduction in the fishy smelling discharge after using LadyBalance for a month. 0,5 per cent of users with the actual problem has experienced 'more' fishy smell or 'much more' fishy smell.

There are 199 users who have problems with discharge with a neutral smell. Among these users 24 per cent experienced that the amount of discharge was 'much less' after using LadyBalance for a month. 34 per cent experienced that it was 'less' while 19 per cent did not experience any difference; 9 per cent experienced 'more' and 3 per cent experienced 'much more' discharge with a neutral smell. Thus, a total of 58 per cent of the users with the problem have experienced an improvement. However, there are a few users who have experienced 'more' discharge with a neutral smell. This is included in the description of the side-effects described for the product.

There are 221 users who have problems with itching or smarting in the vaginal area. Among these users 41 per cent experienced that the problem became 'much less' after using the product for one month and 43 per cent experienced that it became 'less'. Thus, 84 per cent of the users experienced that problems with itching or smarting decrease after using LadyBalance for one month. Ten per cent of the users with the problem experienced 'no difference' while 1 per cent experienced that the problem became 'more' or 'much more' intense.

For the 171 users who used LadyBalance to combat dryness, 46 per cent experienced that the problem occurred 'less' and 28 per cent 'much less' after using LadyBalance for one month. 0,6 per cent of all users had experienced that their problems with dryness had become 'more' prominent after one month's use. Thus, a large part (74%) of the users experienced an improvement in their problems related to dryness after using LadyBalance for one month.

Among the 92 users who indicated the lack of sexual desire as a relevant problem, approximately 28 per cent experienced that the problem was 'less' or 'much less' after one month, while 51 per cent did not notice any difference. 'Do not know' was answered by 21 per cent.

Among the 77 users who indicated lack of sexual endurance as a reason for using LadyBalance, approximately 18 per cent experienced that the problem was 'less' or 'much

less', while the 60 per cent did not notice any difference. 'Do not know' was answered by 21 per cent.

Among the 95 users who indicated recurrent cystitis (bladder infection) as a reason for using LadyBalance, approximately 33 per cent experienced that the problem was 'less' or 'much less', while the 43 per cent did not notice any difference. 'Do not know' was answered by 23 per cent

Among the 48 users who indicated seeking conception as a reason for using LadyBalance, approximately 12 per cent experienced that the problem was 'less' or 'much less', while the 63 per cent did not notice any difference. 'Do not know' was answered by 23 per cent.

Table 7. Effect experienced on the specified problems indicated after one month of use. The percentage is calculated for the users indicating this particular problem as their reason for purchasing LadyBalance .

Effect experienced	Much less	Less	No difference	More	Much more	Do not know	Total per cent	Total number
Discharge with fishy smell (BV)	63,3	32,3	4,8	0,3	0	1,7	100	384
Discharge with a neutral Smell	24,1	33,8	21,6	9,2	2,7	11,4	100	199
Itching and smarting (yeast)	40,7	46,3	10,0	0,5	0,3	5,2	100	221
Dryness (Atrophi)	28,1	45,3	20,3	0,3	0,3	9,2	100	171
Lack of sexual desire	9,8	12,0	50,3	0,5	0,5	28,3	100	92
Lack of sexual endurance	7,8	12,0	47,4	1,7	0,6	30,9	100	77
Recurrent cystitis (bladder infection)	10,5	22,1	43,2	1,1	0	23,2	100	95
Seeking conception	8,3	4,2	62,5	2,1	0	22,9	100	48

N=442

Effect on Vaginal disorders after use for one year

Among the users who have replied the questionnaire 221 have used the product more than one year. The effects are calculated only for customers that have described the particular problem as relevant.

The perceived effect of using LadyBalance vaginal tablets for one year is shown in table 8.

Table 8 shows that among users who seek an improvement to this problem 61 per cent have experienced a 'much less' degree of the fishy smell already after a year's use of LadyBalance. 29 per cent have experienced 'less' smell. Totally, 90 per cent of the users

facing problems related to the fishy smell experienced a reduction in the fishy smelling discharge after using LadyBalance for a year. No user with the actual problem has experienced 'more' fishy smell or 'much more' fishy smell.

There are 109 users who have problems with discharge with a neutral smell. Among these users 29 per cent experienced that the amount of discharge was 'much less' after using LadyBalance for a year. 29 per cent experienced that it was 'less' while 17 per cent did not experience any difference; 7 per cent experienced 'more' and 2 per cent experienced 'much more' discharge with a neutral smell. Thus, a total of 58 per cent of the users with the problem have experienced an improvement. However, there are a few users who have experienced 'more' discharge with a neutral smell. This is included in the description of the side-effects described for the product.

There are 119 users who have problems with itching or smarting in the vaginal area. Among these users 50 per cent experienced that the problem became 'much less' after using the product for one year and 33 per cent experienced that it became 'less'. Thus, 83 per cent of the users experienced that problems with itching or smarting decrease after using LadyBalance for one year. Seven per cent of the users with the problem experienced 'no difference' while no user experienced that the problem became 'more' or 'much more' intense.

For the 98 users who used LadyBalance to combat dryness, 37 per cent experienced that the problem occurred 'less' and 33 per cent 'much less' after using LadyBalance for one year. No user had experienced that their problems with dryness had become 'more' prominent after one year's use. Thus, a large part (70%) of the users experienced an improvement in their problems related to dryness after using LadyBalance for one year.

Among the 53 users who indicated the lack of sexual desire as a relevant problem, approximately 18 per cent experienced that the problem was 'less' or 'much less' after one year, while 40 per cent did not notice any difference. 'Do not know' was answered by 38 per cent.

Among the 54 users who indicated lack of sexual endurance as a reason for using LadyBalance, approximately 18 per cent experienced that the problem was 'less' or 'much less', while the 44 per cent did not notice any difference. 'Do not know' was answered by 33 per cent.

Among the 59 users who indicated recurrent cystitis (bladder infection) as a reason for using LadyBalance, approximately 38 per cent experienced that the problem was 'less' or 'much less', while the 44 per cent did not notice any difference. 'Do not know' was answered by 32 per cent.

Among the 36 users who indicated seeking conception as a reason for using LadyBalance, approximately 17 per cent experienced that the problem was 'less' or 'much less', while the 42 per cent did not notice any difference. 'Do not know' was answered by 42 per cent.

Table 8. Effect experienced on the specified problems indicated after one year of use. The percentage is calculated for the users indicating this particular problem as their reason for purchasing LadyBalance .

Effect experienced	Much less	Less	No difference	More	Much more	Do not know	Total per cent	Total number
Discharge with fishy smell (BV)	61,2	29,3	5,3	0	0	4,3	100	188
Discharge with a neutral Smell	29,4	29,4	17,4	7,3	1,8	14,7	100	109
Itching and smarting (yeast)	49,6	32,8	6,7	0	0	10,9	100	119
Dryness (Atrophi)	36,7	32,7	13,3	0	0	17,4	100	98
Lack of sexual desire	9,4	9,4	50,3	1,9	1,9	37,7	100	53
Lack of sexual endurance	5,6	13,0	44,4	1,9	1,9	33,3	100	54
Recurrent cystitis (bladder infection)	13,6	23,7	30,5	0	0	32,2	100	59
Seeking conception	5,6	11,1	41,7	0	0	41,7	100	36

N=221

Effect on treatment time – one week, month and year

Comparing table 6, 7 and 8 it can be seen that the effect is perceived on the same level for the three time periods.

Using the product for one year or more indicates that the users consider the product as effective, but also that some users need a continuous administration of vaginal lactose to reduce or eliminate vaginal disorders.

Side-Effects of LadyBalance

In this section the side-effects of LadyBalance experienced by the users is described. Table 9 shows the side-effects experienced by the users. The Table shows that most users had a powdery discharge since 49 per cent 'sometimes' and 30 per cent 'always' experienced this side-effect. Moreover, 33 per cent 'sometimes' and 8 per cent 'always' experienced a discomforting, clear discharge. Contrary to this, 50 per cent 'never' experienced any discomforting, clear discharge. Twenty per cent 'sometimes' and 3 per cent 'always' experienced that the tablet slipped out of the vagina.

The other side-effects mentioned in this Table are more seldom. Thus, there are 10 per cent who 'sometimes' experienced itching and 7 per cent who 'sometimes' experienced smarting during the use of LadyBalance. Moreover, 1 per cent 'always' experienced these side-effects. This must be related to the fact that 84 per cent of all users who had

experienced these problems with itching or smarting had 'less' or 'much less' after one week's use of LadyBalance, (ref. Table 6).

Furthermore, 13 per cent 'sometimes' and 1 per cent 'always' experienced a smell of yeast, and 10 per cent 'sometimes' and 1 per cent 'always' experienced an increased urge to pee. Moreover, 10 per cent 'sometimes' and 1 per cent 'always' experienced spot-bleeding and 3 per cent 'sometimes' and 0,3 per cent 'always' experienced headache. A few users (1 per cent) experienced allergic reaction in relation to their use of LadyBalance.

Table 9. Experienced side-effects when applying LadyBalance (Percentage)

	Never	Sometimes	Always	Do not know	Total per cent
The tablet slips out of the vagina	73	20	3	4	100
Powdery discharge	18	49	30	4	100
Discomforting clear discharge	50	33	8	10	100
Itching	83	10	1	7	100
Smarting	86	7	1	6	100
Smell of yeast	75	13	1	11	100
Increased urge to pee	74	11	1	15	100
Spot-bleeding	84	10	1	6	100
Headache	86	3	0,3	11	100
Allergic reaction	93	0,4	0,3	6	100

N=733

To reduce the side-effects it is recommended to use only ½ tablet at a time. The side effects for the respondents using half a tablet or less on the days of use are listed in table 10. The Table shows that most users had a powdery discharge since 54 per cent 'sometimes' and 24 per cent 'always' experienced this side-effect. Compared to all users the percentage for 'always' is 6 percent lower and the 'sometimes' group is 5 percent higher than for all users. Moreover, 39 per cent 'sometimes' and 10 per cent 'always' experienced a discomforting, clear discharge. Compared to all users the percentage for 'always' is 2 percent higher and the 'sometimes' group is 6 percent higher than for all users. Thus only 43 per cent 'never' experienced any discomforting, clear discharge.

Table 10. Experienced side-effects when applying LadyBalance (Percentage) for respondents using ½ tablet or less per day of use

	Never	Sometimes	Always	Do not know	Total per cent
The tablet slips out of the vagina	76	18	2	3	100
Powdery discharge	19	54	24	4	100
Discomforting clear discharge	43	39	10	8	100
Itching	84	9	2	6	100
Smarting	88	5	2	5	100
Smell of yeast	72	13	1	11	100
Increased urge to pee	74	14	1	13	100
Spot-bleeding	81	12	1	7	100
Headache	80	4	1	16	100
Allergic reaction	90	0	1	10	100

N=241

Use of applicator

This chapter describes how the customers experience the effects of using a tablet applicator with the LadyBalance lactose vaginal tablet.

In total 130 respondents indicated that they have used the applicator.

Reason for use of applicator

Table 11 shows, that the majority of respondents use the applicator because they find it more hygienic (63 per cent) or as a help to apply the tablet deep into the vagina (54 per cent).

Table 11. Reasons for choosing to use an applicator. Number and percentage

	Number	Percentage
I find it more hygienic	90	63,4
I do not like using the finger to apply the tablet	28	19,7
Problem to apply the tablet sufficiently deep	76	53,5
The tablet slips out of the vagina	11	7,8
I did not know if it was needed	8	5,6
Do not know	6	4,2
Other	6	4,2

N=142

Note: The users can select more than one answer and the percentages must not add up to 100.

Side effects using applicator

Table 12 shows, that the majority of respondents have not observed any problems by using the applicator (72 per cent).

Table 12. Side effects when using applicator. Number and percentage

	Number	Percentage
Difficult to fix the tablet in the applicator	5	3,5
Difficult to lead into the vagina	5	3,5
Difficult to press the tablet out of the applicator	3	2,1
The applicator gives bruises in the vagina	5	3,5
No problems observed	120	84,5
Other	11	7,8

N=142

Note: The users can select more than one answer and the percentages must not add up to 100.

Re-use of single use applicator

In total 65 respondents (46 per cent) indicate that they re-use the applicator, even it is a single-use item. These describe how they clean the applicator, as shown in table 13. The

table shows, that 38 percent wash it with soap, 27 per cent disinfects it also, while 20 per cent only rinse the applicator between uses.

Table 13. Cleaning method for re-used applicator. Number and percentage

	Number	Percentage
No cleaning	1	1,5
Using a cloth	3	4,6
Rinsing	13	19,7
Wash with soap	25	37,9
Wash and disinfect	18	27,3
Dish washer	1	1,5
Do not know	1	1,5
Other	4	6,1

N=66

Perceived effect of the lactose tablet with or without using the applicator

In total 67 respondents indicate that they have used the ladyBalance lactose tablets both with and without applicator.

Table 14 shows that among users who seek an improvement to discharge with fishy smell 31 per cent have experienced a 'much less' degree of the fishy smell when using the applicator. 28 per cent have experienced 'less' smell. Totally, 59 per cent of the users facing problems related to the fishy smell experienced a reduction in the fishy smelling discharge when using the applicator with the vaginal tablet. No user with the actual problem has experienced 'more' fishy smell or 'much more' fishy smell when using the applicator.

There are 33 users who have problems with discharge with a neutral smell. Among these users 27 per cent experienced that the amount of discharge was 'much less' when using the applicator. 15 per cent experienced that it was 'less' while 36 per cent did not experience any difference; 6 per cent experienced 'more' and 3 per cent experienced 'much more' discharge with a neutral smell. Thus, a total of 42 per cent of the users with the problem have experienced an improvement when using the applicator. However, there are a few users who have experienced 'more' discharge with a neutral smell.

There are 30 users who have problems with itching or smarting in the vaginal area. Among these users 20 per cent experienced that the problem became 'much less' when using the applicator and 23 per cent experienced that it became 'less'. Thus, 43 per cent of the users experienced that problems with itching or smarting decrease after using the applicator together with the tablet. 33 per cent of the users with the problem experienced 'no difference' while no user experienced that the problem became 'more' or 'much more' intense.

For the 26 users who used LadyBalance to combat dryness, 15 per cent experienced that the problem occurred 'less' and 12 per cent 'much less' when using the applicator while 46 per cent did not experience any difference;. No user had experienced that their problems with dryness had become 'more' prominent when using the applicator.

Table 14. Effect experienced on the specified problems indicated with use of applicator compared to use without applicator. The percentage is calculated for the users indicating this particular problem as relevant for them.

Effect experienced	Much less	Less	No difference	More	Much more	Do not know	Total per cent	Total number
Discharge with fishy smell (BV)	31,0	27,6	34,5	0	0	6,9	100	58
Discharge with a neutral Smell	27,3	15,1	36,4	6,1	3,0	12,1	100	33
Itching and smarting (yeast)	20,0	23,3	33,3	0	0	23,3	100	30
Dryness (Atrophi)	15,4	46,2	46,2	0	0	26,9	100	26

N=67

Table 15 shows the most prominent side-effects experienced by the users with use of applicator compared to use without applicator. For the problem that experienced that the tablet slipped out of the vagina, 25 per cent indicate 'much less' and 9 per cent 'less'.

Contrary 5 per cent indicate 'more' and 2 per cent 'much more'.

As for powdery discharge - the most prominent side effect – 8 per cent indicate 'much less' and 22 per cent 'less'. Contrary 5 per cent indicate 'much more'

The discomforting clear discharge was 'much less' for 8 per cent and 'less' for 5 percent Spot bleeding was considered a risk by using the applicator. But only 3 per cent indicated 'more' on this issue, while 9 percent indicated 'much less' and 2 per cent 'less'.

Table 15. Effect experienced on the side-effects indicated with use of applicator compared to use without applicator.

Effect experienced	Much less	Less	No difference	More	Much more	Do not know	Total per cent
The tablet slips out of the vagina	24,6	9,2	43,1	4,6	1,5	16,9	100
Powdery discharge	7,7	21,5	50,8	0	4,6	15,4	100
Discomforting clear discharge	7,7	4,62	58,5	1,5	0	27,7	100
Spot-bleeding	9,2	1,5	43,8	3,1	0	43,1	100

N=65

Effects on recurrent cystitis (bladder infection)

As scientific literature indicates that recurrent cystitis may be influenced by the presence of bacterial vaginosis (BV), questions related to this topic were included in the questionnaire, recognizing that a treatment effect relation is very unlikely to obtain in a user survey.

In total 214 women (30 per cent) answered, that they have had recurrent cystitis at some time during the last 10 years.

The women were asked to inform about symptoms for or diagnosis of bacterial vaginosis in the period of recurrent cystitis. In total 40 per cent indicated no BV, 17 per cent had diagnosed BV and 22 per cent had the typical symptoms for BV. In total 39 per cent were likely affected by BV in the period with cystitis.

Table 16. The occurrence of diagnosed or probable bacterial vaginosis in the period of recurrent cystitis

	Number	Percentage
No bacterial vaginosis	86	40,2
Diagnosed bacterial vaginosis	36	16,8
Discharge with fishy smell	46	21,5
Vaginal liquid with pH higher than 5	1	0,5
Do not know	45	21,0

N=214

The same respondents were asked about treatment of bacterial vaginosis in the period of recurrent cystitis. Table 17 shows the result both calculated for all respondents and for those being treated only. Metronidazol has been the dominant treatment with 57 per cent of the treatments.

Table 17. Treatment of bacterial vaginosis in the period of recurrent cystitis. Percentage for all respondents with recurrent cystitis and for those being treated.

	Number	Percentage of 214 respondents	Percentage of 96 treated respondents
No treatment	118	55,1	-
Metronidazol	55	25,7	57,3
Clindamycin	13	6,1	13,5
LadyBalance lactose tablets	37	17,3	38,5
Probiotika	22	10,3	22,9
Other (do not remember antibiotic)	9	4,2	9,4

N=214

The respondents were asked about their perception of treatment of bacterial vaginosis in relation to recurrent cystitis. Table 18 shows the result only for those being treated. In total 29 per cent evaluate that cystitis is 'much less' or 'less' after treatment of BV. 44 per cent have no opinion on the relation.

Table 18. Perception of effect of treatment of bacterial vaginosis against recurrent cystitis. Percentage for those being treated.

Effect experienced	Much less	Less	No difference	More	Much more	Do not know	Total per cent
Occurrence of Cystitis after BV treatment	9,9	18,5	25,9	1,9	0	43,8	100

N=162

The number of episodes of cystitis in the last 10 years for all respondents indicating recurrent cystitis is given in table 19a and the number of episodes while the respondent has been using LadyBalance lactose vaginal tablets in table 19b.

To get an indication of the frequency of episodes in the two situations an average number of episodes was calculated. As some answer options were a range, the mean of this range was used for calculation. Thereby the average number of episodes for all affected respondents is 5,5 while the number of episodes while the respondent has been using LadyBalance lactose vaginal tablets is 1,3. The similar calculated average time these users had been using LadyBalance vaginal tablets was 1,5 years

Table 19a. Number of episodes of cystitis in the last 10 years. Number and percentage for the respondents having had recurrent cystitis

Answer options	Number	Percentage
0	-	-
1-2	47	21,9
3-5	88	40,9
6-10	42	19,5
More than 10	38	17,7

N=214

Table 19b. Number of episodes of cystitis in the period while the respondent has been using LadyBalance lactose vaginal tablets. Number and percentage for the respondents having had recurrent cystitis

Answer options	Number	Percentage
0	103	48,6
1	49	23,1
2-3	36	17,0
4-6	16	7,1
More than 6	9	4,3

N = 212

LadyBalance, conception and pregnancy

The users were asked about the use of LadyBalance while trying to become pregnant and during the pregnancy – and their perception of the influence on the outcome.

69 users reported having used LadyBalance in a period wishing to conceive and up to 2 years before. Out of these 45 had succeeded to conceive.

Table 20 shows whether the respondents, that have conceived, had used lactose tablets up to the time of conception. It can be seen that 70 per cent had been using LadyBalance when conceiving.

Table 20. Whether the respondent used LadyBalance lactose tablets in the period of conception - and how long before. The respondents having concealed only.

Answer options	Number	Percentage
No	13	29,6
Yes, less than a month	9	20,5
Yes 1-3 months	11	25,0
Yes 4-12 months	4	9,1
Yes, more than 12 months	7	15,9

N = 44

The question whether any side-effects were observed by using LadyBalance tablets during the pregnancies was answered by 25 having used the tablet during pregnancy. Of these 24 (96 per cent) experienced no problems. One user stated that she had bleeding when she started to use the tablets, but she did not know of any relation between the two.

The outcome of the pregnancy

The women were asked whether they had given birth or had an abortion in the period of using LadyBalance vaginal tablets and up to 2 years before. In total 32 respondents had a termination of pregnancy either by giving birth or spontaneously abortion. The numbers are though small.

Table 21. Outcome of the pregnancy for LadyBalance users. Time for abortion or birth (Number and percentage)

	Before week 30	Week 30-34 incl.	Week 34-37 incl.	Week 38-39 incl.	Week 40	Week 41-42 incl.	After week 42	Total
Number	6	0	2	4	5	12	3	32
Percentage	18,8	0	6,3	12,5	15,6	37,5	9,4	100

Table 22 shows how many of the respondents used LadyBalance vaginal tablets before birth. The majority of 65 per cent did not use vaginal tablets, while 12-15 per cent used vaginal tablets continuously, sporadic or at beginning of pregnancy. The numbers are though small.

Table 22. Did you use of LadyBalance before the birth /abortion. (Number and percentage)

	No	Yes, continuous during pregnancy	Yes sporadic during pregnancy.	Yes, shortly before birth.	Yes, at the beginning of pregnancy	Total
Number	22	4	5	0	4	34
Percentage	64,7	11,8	14,7	0	11,8	100

Table 23 shows the distribution of the (few) birth terms related to the use of LadyBalance vaginal lactose tablets.

Table 23. Distribution time of birth and use of LadyBalance vaginal tablets for all respondents having given birth or spontaneous abortion (Numbers)

Time of birth / abortion	The use of LadyBalance during pregnancy					Total
	No	Yes, continuous during pregnancy	Yes sporadic during pregnancy.	Yes, shortly before birth.	Yes, at the beginning of pregnancy	
Before week 30	5	-	-	-	1	6
Week 31-33 incl.	-	-	-	-	-	0
Week 34–37 incl.	1	1	-	-	-	2
Week 38-39 incl.	1	1	1	-	1	4
Week 40	3	-	1	-	-	4
Week 41-42 incl.	8	1	3	-	1	13
After week 42	1	1	-	-	1	3
Total	19	4	5	0	4	32

LadyBalance and cervical lesions

The respondents were asked to inform of diagnosing cervical lesions (precursors of cervical cancer) in the last 5 years. In total 83 respondents stated that cervical lesions were diagnosed.

Cervical lesion are reinvestigated after 6 or 12 months. 21 respondents (26,3 per cent) stated that further treatment was necessary, while for 56 no further treatment was needed.

Table 24 describes the relation between needed further treatment, diagnose of BV and use of LadyBalance vaginal tablets.

Table 24. Distribution need to have a follow-up treatment for cervical lesions, use of LadyBalance vaginal tablets and presence of symptoms of BV for all respondents having been diagnosed with cervical lesions. (Numbers)

Follow-up treatment needed	The use of LadyBalance between initial diagnosis and follow-up					
	None		Sporadic		Min. 2 per week	
	BV negative	BV positive	BV negative	BV positive	BV negative	BV positive
Yes	5	4	3	8	0	1
No	8	32	7	22	0	2
Total	13	36	10	30	0	3

Conclusion

Use of Ladybalance vaginal tablets

Based on the survey of users of LadyBalance 2017 it can be concluded that the users in average use 6,3 tablets per month.

Special conditions

There is evidence or indications in the literature, that bacterial vaginosis has an adverse effect on the following conditions:

Recurrent cystitis – Gilbert NM, O'Brien VP, Lewis AL (2017) Transient microbiota exposures activate dormant *Escherichia coli* infection in the bladder and drive severe outcomes of recurrent disease. *PLoS Pathog* 13(3): e1006238. doi:10.1371/journal.ppat.1006238

Conception - Haahr et al. (2016): Abnormal vaginal microbiota may be associated with poor reproductive outcomes: A prespective study in IVF patients. *Hum.Reprod.Advance Access* 0(0) 1-9.

Cervical lesions- Motevaseli, E et al. (2013): Normal and tumour cervical cells respond differently to vaginal lactobacilli, independent of pH and lactate. *Journal of Medical Microbiology* (2013), 62, 1065–1072; DOI 10.1099/jmm.0.057521-0 ; significant improvement in unpublished Vietnamese trial with Ladybalance vaginal tablets.

Therefore questions related to these issues were included in the survey even it was not expected to get any conclusive information. Indications were looked for.

Effect of LadyBalance vaginal tablets

The frequency of respondents relevant for these special issues were respectively 24 percent for recurrent bladder infection, 10 percent for seeking conception and 11 percent for cervical lesions.

As in former surveys, the majority of users seek relief for discharge with a fishy smell, while itching/smartering and dryness come in as the second and third most dominant reason to use LadyBalance vaginal tablets.

The majority of the users experienced that their discomforts relating to discharge with a fishy smell, discharge with a neutral smell, itching/smartering and dryness improved by the application of LadyBalance for just one week. 83 per cent of the users purchased LadyBalance due to discharge with a fishy smell and 93 per cent of these experienced an improvement of the problem after one week's application. Among users who had the problem of a neutral-smelling discharge 55 per cent experienced an improvement within one week. Itching and smartering are the normal symptoms of yeast infection. 84 per cent of the users, who bought LadyBalance for the purpose of relief from the discomforts of itching or smartering, experienced that there was less discomfort after one week's application. For users purchased LadyBalance to improve their problems pertaining to dryness 70 per cent have experienced an improvement of the problem after applying LadyBalance for one week. Only a few users have applied LadyBalance to improve sexual desire and sexual endurance an only about 20 per cent experienced an improvement in these fields.

Only a very small part of the users experienced a worsening of their problems by the application of LadyBalance. It is found that only 1-2 per cent experienced an aggravation of the afore-mentioned problems by using LadyBalance. However, 12 per cent

experienced that the problem of discharge with a neutral smell worsened by applying LadyBalance.

The perceived effect is very similar comparing after one week, after one month and after one year.

For the longer periods the evaluation of effect also included recurrent cystitis, where 32 per cent found an improvement after one month. For seeking conception 13 percent stated an improvement after one month. After one year the percentages were 37 for recurrent cystitis and 17 for seeking conception.

Side effects

When questioned about side-effects 41 per cent of the users experienced that they 'sometimes' or 'always' had a discomforting clear discharge by using LadyBalance.

Another side-effect experienced by many women is a powdery discharge (79 per cent). Furthermore, 10 – 14 per cent sometimes or always experienced side-effects in the form of itching, smarting, smell of yeast, spot-bleeding and increased urge to pee, while an even smaller part (3 pct.) headache. Only 0,7 per cent state allergic reaction as a side effect.

Using ½ tablet

For users having the major side effects is recommended to use only ½ tablet. The side effects were calculated for users stating that they use ½ tablet or less per day when using the tablet. For these 49 per cent of the users experienced that they 'sometimes' or 'always' had a discomforting clear discharge by using LadyBalance. The powdery discharge was affecting 78 per cent. Comparing table 9 and table 10 it can be seen that most side effects are slightly improved by using ½ tablet, but discomforting clear discharge is occurring slightly more.

Applicator

Since last survey LadyBalance started to offer a single-use tablet applicator. Several questions were related to the use of applicator and the experience with it. Of the 130 having used the applicator the main reason to do so was because they find it more hygienic, or problems in applying the tablet sufficiently deep into the vagina. Generally no problems were observed by using the applicator, though 4 per cent state that the applicator can give bruises in the vagina.

Even it is a single-use applicator, 46 per cent of the users indicate that they reuse the applicator. Most wash it with soap and slightly less also use disinfectant. The LadyBalance lactose tablet is considered an effective barrier against unwanted bacteria – therefore the reuse of the applicator is not considered a major problem, but it must be considered in the risk analysis for the applicator.

The 67 respondents having used LadyBalance vaginal tablets with and without applicator described their perception of the effect of the tablet with applicator compared to without applicator. 59 per cent of the users purchased LadyBalance due to discharge with a fishy smell experienced an improvement of the problem using the applicator. Among users who had the problem of a neutral-smelling discharge 42 per cent experienced an improvement when using the applicator. Itching and smarting are the normal symptoms of yeast infection. 43 per cent of the users, who bought LadyBalance for the purpose of relief from the discomforts of itching or smarting, experienced that there was less discomfort when using the applicator. For users purchased LadyBalance to improve their problems

pertaining to dryness 62 per cent have experienced an improvement of the problem when using the applicator.

As for the side effects, the experience that the tablet slips out of the vagina is reduced by 34 per cent and the powdery discharge by 29 per cent. For the other side effect the improvement is around 11 per cent.

Overall the use of applicator means a more effective use of the lactose tablet for those women having minor problems with the use. As clear discharge can be a natural effect of the lactose metabolism, it is understandable that for some women this effect becomes more dominant. Women are very differently shaped, and have different approach to touching themselves in the vaginal area. Therefore the recommendation for use of applicator is, that use of applicator should be used in case the effect of the lactose tablet is not sufficient, and/or the side effects of powdery discharge or the tablet slips out of the vagina are prominent.

Some diagnoses where BV may be a major risk factor have been included in the survey. It is though not possible to get clear indications of the cause-effect in these cases. First it is not always clear for the patient whether BV is present. Thereafter we do not have any evidence of the effect of the treatment applied. The results may indicate good hypothesis for further research.

Cystitis

The questions related to recurrent cystitis (bladder infection) confirmed, that this is a major problem, as 30 per cent of the women stated, that they had this problem. The relation between this condition and bacterial vaginosis was only partly confirmed, as only 39 per cent of the respondents stated that they had BV or symptoms thereof during the period of recurrent cystitis. Forty percent stated no BV and 21 per cent did not know. The treatment is described, but as the cause- effect is more complex (e.g. was the treatment effective?) it is not possible to draw any conclusions from this. Asking the respondents to evaluate the effect of BV treatment against recurrent cystitis, 28 percent considered the BV treatment to have helped against cystitis.

By using a calculation mean for the answer options it was shown, that for all users being affected by recurrent cystitis, the average number of episodes was 5,5 over 10 years. The number of episodes when using LadyBalance vaginal tablets was 1,3 over 1,5 years. Directly comparing no. of episodes per year does not indicate a positive effect of using LadyBalance vaginal tablets against recurrent cystitis. But it is a question whether the respondents do remember all episodes 10 years back and for future surveys a shorter period must be used. The possible positive effect is underlined with the large percentage (49 per cent) not having had episodes of cystitis while using LB.

Conception and pregnancy

69 users reported having used LadyBalance while trying to conceive or two years before, and 45 had become pregnant. Their reporting of side effects was similar to the non-pregnant users, and no special side-effects related to pregnancy were described. The period using LadyBalance was very variable. Out of the 44 answers, 30 per cent had not used LadyBalance before conception, while the remaining 70 per cent had used it in periods for less than a month till more than 12 months. The 31 conceptions therefore show that the use of LadyBalance vaginal tablets is not preventing conception. Of the 32 abortions/births reported by LadyBalance users, 6 were born before week 30, 6 at week

30-39, 5 at week 40, 12 at week 41-42 and 3 and week 42. An evaluation referring to normal outcome is not possible on this material.