

An updated User
Survey
Of
LadyBalance[®]
Vaginal Tablets

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Update of user survey

The present report is the second report of user experiences with Ladybalance. The present report is based on a survey which is generally identical with the survey on which the first report from 2009 is based. However, in the present survey the questions related to different periods of use have been simplified, and information related to use during pregnancy are included. Moreover the user perception of the result of a slightly changed production process is evaluated.

Collection of Data

This study is based on data from an electronic questionnaire amongst 344 users of LadyBalance lactose tablets.

On 13th May 2013 an e-mail was sent to all customers who recently had purchased LadyBalance vaginal tablets in the Internet shop. 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 one and two weeks after the initial e-mail message. The questionnaire was sent to 1027 customers all of whom had given their e-mail addresses when they purchased LadyBalance. Out of these 344 had completed the whole questionnaire or parts of it. 63 abstained from participating and 19 e-mail addresses were not accepted. Disregarding the addresses that were not in use the overall response rate was 34 per cent. This is considered satisfactory since such questionnaires often get caught in the spam filters.

The LadyBalance Users

The median age of the women was 37 years with minimum 16, and maximum of 70 years. 25 per cent were above 46 years. They had in average used LadyBalance for 27 months with 25 per cent using it for 6 months or less, and 25 per cent using it for more than 4 years. The users reported conditions and practices relevant for the vaginal health as shown in table 1 and 2.

Table 1. Conditions relevant for vaginal health encountered before or during the period of use of LadyBalance vaginal tablets. Number and percentage for which they apply.

	Number	Percentage
Diabetes	2	1
Conisatio	17	5
Hysterectomy	7	2
Menopause	43	13
Allergic to milk or cows	17	5

N=324

Table 2. Practices relevant for vaginal health during the period of use of LadyBalance vaginal tablets. Number and percentage for which they apply.

	Number	Percentage
Regular menstrual period	220	68
Used contraceptive pill	88	27
Used IUD with hormones (progesterone)	59	18
Used non-hormone IUD (all other variants)	31	10
Sexually active several times per day	90	28

N=323

The Use of LadyBalance

Among the participants in the survey 4 have not used LadyBalance and one did not know. The remaining 339 users were questioned about their use of LadyBalance.

As shown in Table 3 the majority of users (38%) applied 2½ - 5 tablets per month, 27 per cent used two tablets or less per month while only 19 per cent used more than 10 tablets per month. The majority did not use LadyBalance daily. The figures mentioned can be recalculated to state an approximate average consumption of LadyBalance tablets of 5.7 per month.

Table 3. Number of LadyBalance tablets per month the users apply (Number and percentage)

	Number	Percentage
½ - 2 tablets	89	27
2½ - 5 tablets	126	38
5½ - 10 tablets	64	19
10½ - 20 tablets	35	10
20½ - 30 tablets	8	2
More than 30 tablets	0	0
Do not know	14	4

N= 337 users

Table 4 shows when the users apply LadyBalance. It appears that only seven per cent use the tablets continuously. Other users apply the tablets primarily when they observe a problem and have a reason for using LadyBalance (75 per cent). Though 30 per cent use LadyBalance regularly after menstruation, 28 per cent use it after intercourse and 16 per cent used it when sexual activity is anticipated.

The “Other” reasons to use Ladybalance include (one of each) after treatment with antibiotics, chemotherapy and use of sex toys.

Table 4. Occasions when LadyBalance was used (Number and percentage)

	Number	Percentage
Always	24	7
After menstruation	102	30
After intercourse	94	28
In anticipation of sexual activity	53	16
When a problem is observed	254	75
Never	1	1
Do not know	1	1
Others	28	8

N= 337 users

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

Table 5 shows the problems the users of LadyBalance wished to remedy. It shows that the majority (76 per cent.) of customers have purchased LadyBalance for the purpose of reducing the problem of a fishy smelling discharge. 36 per cent have bought the product to improve problems related to itching or a smarting sensation. 24 per cent wished to improve their problems with dryness and 10 per cent wished to reduce problems relating to a neutral smelling discharge . Moreover, 3 per cent wanted to improve their lack of sexual desire and 2 per cent wished to improve their sexual endurance. Primarily mentioned under others are bad smell and fungal infection.

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

	Number	Percentage
Discharge with a fishy smell	256	76
Discharge with a neutral smell	35	10
Itching/Smarting	122	36
Dryness	81	24
Lack of sexual desire	9	3
Lack of sexual endurance	5	2
Others	26	8

N=335

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

Effects of LadyBalance

This chapter describes how the customers experience the effects of LadyBalance after using it for one week. The effects are calculated only for customers that have described the particular problem as a reason for purchasing LadyBalance.

Effect on Discharge with a Fishy Smell

As shown in Table 5 a fishy smelling discharge is the problem most of the users tried to remedy with LadyBalance. Table 6 shows that among users who seek an improvement to this problem 68 per cent have experienced 'much less' fishy smell already after a week's

use of LadyBalance. 26 per cent have experienced 'less' smell. Totally, 94 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. One per cent of users with the actual problem has experienced 'more' fishy smell while two per cent has experienced 'much more' fishy smell.

Table 6. Effect experienced on discharge with fishy smell indicated after one week for the users indicating this particular problem as their reason for purchasing LadyBalance (Percentage)

	Much less	Less	No difference	More	Much more	Do not know
One week	68	26	2	0	1	2

N=254

Effect on Discharge with a Neutral Smell

There are 33 users who have problems with discharge with a neutral smell and have indicated that this particular problem is their reason for using LadyBalance. Among these users 36 per cent experienced that the problem of discharge was 'much less' after using LadyBalance for a week. 33 per cent experienced that it was 'less' while 6 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 69 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 elaborated in the description of the side-effects experienced.

Table 7. Effect experienced on discharge with a neutral smell indicated after one week for the users indicating this particular problem as their reason for purchasing LadyBalance (Percentage)

	Much less	Less	No difference	More	Much more	Do not know
One week	36	33	6	6	3	15

N=33

Effect on Itching and Smarting

Some users (121) have purchased LadyBalance to remedy itching or smarting in the vaginal area. Among these users 46 per cent experienced that the problem became 'much less' after using the product for one week and 49 per cent experienced that it became 'less'. Thus, 95 per cent of the users experienced that problems with itching or smarting decrease after using LadyBalance for one week. 8 per cent of the users with the problem experienced 'no difference' while one per cent experienced that the problem became 'more' intense and 3 per cent experienced it as 'much more'.

Table 8. Effects experienced on itching or smarting indicated after one week for the users indicating this particular problem as their reason for purchasing LadyBalance (Percentage)

	Much less	Less	No difference	More	Much more	Do not know
One week	46	39	8	1	3	3

N=121

Dryness

For the users who purchased LadyBalance to combat dryness, 79 per cent experienced that the problem occurred 'less' or 'much less' after using LadyBalance for one week. One per cent of all users had experienced that their problems with dryness had become 'more' prominent after one week's use. Thus, a large part of the users experienced an improvement in their problems related to dryness after using LadyBalance for one week.

Table 9. Effects experienced on dryness indicated after one week for the users indicating this particular problem as their reason for purchasing LadyBalance (Percentage)

	Much less	Less	No difference	More	Much more	Do not know
One week	35	44	19	0	1	1

N=81

Lack of Sexual Desire

Among the few users who indicated the lack of sexual desire, approximately one half of them experienced that the problem was 'less' or 'much less', while the other half did not notice any difference. Only 9 users had indicated that lack of sexual desire was their reason for using LadyBalance.

Table 10. Effects experienced on lack of sexual desire indicated after one week for the users indicating this particular problem as their reason for purchasing LadyBalance (Percentage)

	Much less	Less	No difference	More	Much more	Do not know
One week	22	33	33	0	0	11

N=9

Lack of Sexual Endurance

Only five users had indicated lack of sexual endurance as the reason for using LadyBalance, therefore, it is difficult to generalise from these answers. But of these 5

persons, 3 had experienced that their problem regarding lack of sexual endurance became 'much less' by using LadyBalance, while 1 found that 'no difference'.

Table 11. Effects experienced on lack of sexual endurance indicated after one week for the users indicating this particular problem as their reason for purchasing LadyBalance (Percentage)

	Much less	Less	No difference	More	Much more	Do not know
One week	60	0	20	0	0	20

N=5

Side-Effects of LadyBalance

In this section the side-effects of LadyBalance experienced by the users is described. Table 12 shows the side-effects experienced by the users after using the product for one week or immediately after a pause. The Table shows that most users had a powdery discharge since 51 per cent 'sometimes' and 27 per cent 'always' experienced this side-effect. Moreover, 32 per cent 'sometimes' and 10 per cent 'always' experienced a discomforting, clear discharge. Contrary to this, 47 per cent 'never' experienced any discomforting, clear discharge. 22 per cent 'sometimes' and 2 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 12 per cent who 'sometimes' experienced itching and 11 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 85 per cent of all users who had bought LadyBalance to remedy problems with itching or smarting had 'less' or 'much less' after one week's use of LadyBalance, (ref. Table 8).

Table 12. Whether the users experienced the following side-effects after the first week's application of LadyBalance or immediately after a pause (Percentage)

	Never	Sometimes	Always	Do not know	Total per cent
The tablet slips out of the vagina	71	22	2	5	100
Powdery discharge	17	51	27	4	100
Discomforting clear discharge	47	32	10	11	100
Itching	78	12	1	8	100
Smarting	80	11	1	8	100
Smell of yeast	72	13	1	13	100
Increased urge to pee	74	10	2	15	100
Spot-bleeding	82	8	2	9	100
Headache	80	3	2	15	100

N=330

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, 8 per cent 'sometimes' and 2 per cent 'always' experienced spot-bleeding. A few users experienced headache in relation to their use of LadyBalance.

Table 13 shows the side effects of LadyBalance after one months' application. Among the users who have replied the questionnaire 94 per cent have used the product more than one month. The side effects are in the same level as after one week (Table 12).

Table 13. Whether the users experienced side-effects after the application of LadyBalance for one month (Percentage of those having used LadyBalance for one month)

	Never	Sometimes	Always	Do not know
The tablet slips out of the vagina	69	26	2	4
Powdery discharge	24	52	21	3
Discomforting clear discharge	51	31	9	8
Itching	78	11	2	8
Smarting	82	9	2	7
Smell of yeast	74	13	1	12
Increased urge to pee	76	11	1	12
Spot-bleeding	86	7	1	5
Headache	81	5	0	14

N=246

Table 12 and 13 compared shows that the level of side effects is quite similar after one week and one month's use.

LadyBalance and pregnancy

The users were asked about the use of LadyBalance during the pregnancy – and their perception of the influence on the outcome.

24 users reported having used LadyBalance in a period wishing to conceive. Out of these 11 had succeeded to conceive.

Seventeen users reporting having used LadyBalance during pregnancy. Out of these 17 per cent reported increased urge to pee as a side effect. This seems higher than for non-pregnant users, but this is also a common condition for pregnant women. One person (6%) reported spot-bleeding. Their reporting of side effects was similar to the non-pregnant users. None of the pregnant women used the option to report other side effects.

Table 14. Whether the pregnant users experienced side-effects after the application of LadyBalance (Percentage)

	Percentage
No side effects	83
Increased urge to pee	17
Spot-bleeding	6

N=18

Five users report having used LadyBalance during the last 3 months of the pregnancy. All of them reported having used no other remedies during these last 3 months.

The outcome of the pregnancy

The 17 pregnant users reported the outcome of the pregnancy as follows in Table 15. The frequency of preterm birth is low – only 2 births are 2-4 weeks preterm, and no births are more than 4 weeks preterm.

Table 15. Outcome of the pregnancy for LadyBalance users (Percentage)

	Child born after term	Child born at term	Child born 2-4 weeks before term	Child born >4 weeks before term	Child born by cesarian	Abortion	Child not yet born	Total number
Percentage	18	24	12	0	18	12	29	17

N=17

Perception amongst persons allergic to milk

Even the product carries a warning for persons allergic to milk, 15 of the users reported having used LadyBalance even being allergic to milk.

Comparing the few data for the allergic users with the general data (Table 5 and 12), there is no clear difference in the perception of the effect and the level of side effects. Though the level of spot bleeding seems somewhat higher for allergic users (20 per cent reporting 'sometimes' compared to 8 per cent 'sometimes' and 2 per cent 'always' for the users in general.

The allergic users had been using LadyBalance for 28 months in meridian.

Table 16. Users' problems and reasons for purchasing LadyBalance for persons reporting to be allergic to milk (Number and percentage)

	Number	Percentage
Discharge with a fishy smell	9	60
Itching/Smarting	9	60
Dryness	3	20

N=15

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

Table 17. Whether the users experienced the following side-effects after the first week's application of LadyBalance or immediately after a pause for persons reporting to be allergic to milk or cows (Percentage)

	Never	Sometimes	Always	Do not know	Total per cent
Itching	93	0	0	7	100
Smarting	80	13	0	7	100
Spot-bleeding	67	20	0	14	100
Headache	73	7	0	20	100

N=15

Effect of change in production method

A slight modification in the production method of the tablets was introduced in June 2012. For users having used both old and new version, their perception of differences in effect and side effects were asked for. Only 27 could identify having used both versions. Their perception is listed in Table 16 and 17. Most users experienced no difference. For those reporting a difference, it was in nearly all cases positive for the new version.

Table 18. Effects experienced on differences in effect between old and new (2012) versions of LadyBalance lactose vaginal tablet (Percentage)

	Much better	Better	No difference	Worse	Much worse	Not relevant
Effect against bad smell	11	15	52	7	0	15
Effect against itching and smarting	4	11	63	0	0	22
Effect against dryness	0	7	59	0	0	33

N=27

Table 19. Effects experienced on differences in side effects between old and new (2012) versions of LadyBalance lactose vaginal tablet (Percentage)

	Much less	Less	No difference	More	Much more	Not relevant
Discharge from the product	11	7	59	0	4	19
Clear discharge	11	4	56	7	0	22
Spot-bleeding	4	0	52	0	0	44
Increased urge to pee	4	0	48	0	0	48

N=27

Conclusion

Based on the survey of users of LadyBalance it can be concluded that the users are in median 37 years old (25 per cent below 46). They have in average been using LadyBalance tablets for 27 months, and 25 per cent have been using it for more than 4 years. The average use can be calculated to approximately 5.7 tablets per month. The majority of the users experienced that their discomforts relating to discharge with a fishy smell, discharge with a neutral smell, itching/smarting and dryness improved by the application of LadyBalance for just one week. 76 per cent of the users purchased LadyBalance due to discharge with a fishy smell and 94 per cent of these experienced an improvement of the problem after one week's application. 85 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 after one week's application. Among users who had the problem of a neutral-smelling discharge 69 per cent experienced an improvement within one week. Itching and smarting are the normal symptoms of yeast infection. A substantial part of the users purchased LadyBalance to improve their problems pertaining to dryness (24 pct.), and among these 79 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 but it is seen that 55-60 per cent of all users 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, 9 per cent experienced that the problem of discharge with a neutral smell worsened by applying LadyBalance. When questioned about side-effects 42 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. 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 (5 pct.) experienced headache.

24 users reported having used LadyBalance while trying to conceive, and 11 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. Of the 9 children reported born by LadyBalance users, none of them were born before 4 weeks before term, 2 were born between 2 and 4 weeks before term and 7 were born at or after term.

15 users reporting to be allergic to milk have been using LadyBalance despite the warning on the label. These have been using Ladybalance for 28 months in meridian, and experienced no special side effects by using LadyBalance.

The new version (from June 2012) of the LadyBalance vaginal lactose tablet has effects similar to the former version. For the 27 users identifying having used both versions no difference was experienced. This applies for 52 -63 per cent related to the effect towards the problem being the reason to purchase LadyBalance, and 48 – 59 per cent related to side effects. With the new version substantial improvement was noticed for discharge with bad smell (11 per cent 'much better' and 15 per cent 'better') and for itching and smarting (4 per cent 'much better' and 11 per cent 'better'). The improvement on dryness was less. Generally the side effects were reduced.