

LadyBalan

KS DOMSTOL

No	Heading	Content			
1	Description of the medical device				
1.1	Description of the medical device	This product is a vaginal tablet of 1200 (1100-1300) mg dividable into two pieces, consisting of 96 (95,5-99,9) g lactose monohydrate, Ph. Eur grade, (0,3-2,0) g magnesium stearate, veg., Ph. Eur grade, (0,1-2,5) g silicium dioxide (Syloid AL-1 FP). The components are mixed and pressed into tablet			
		without further additives or processing aids.			
1.2	List of accessories and fittings	96 (95,5-99,9) % lactose monohydrate, Ph. Eur grade (0,3-2,0) % magnesium stearate, veg. , Ph. Eur grade, (0,1-2,5) % silicium dioxide (Syloid AL-1 FP).			
1.3	Purpose/ Instruction	LadyBalance vaginal tablets is used to treat and prevent:			
		Bacterial vaginosis (BV)			
	San and	Unpleasant vaginal odour and discharge			
		Vaginal dryness and itching			
	14. J.	Vaginal irritation and soreness			
1.4	Instruction	The tablet must be applied deep into the vagina by a finger. Moistening the tablet may help insertion.			
		The women will use the product according to percepted need - whenever she feels an imbalance or bad smell and in periods where she by experience has problems (after the period, after unprotected sex).			
		Normal dosage is $\frac{1}{2}$ - 1 tablet at a time, with between 3 and 20 inserts per month. To prevent and suppor treatment of bacterial vaginosis, maintain a healthy vagina $\frac{1}{2}$ - 1 tablet is used every day.			
		LadyBalance can be used during pregnancy and breast feeding but see your doctor if you have an infection during pregnancy.			
1.5	Contraindications	The product should not be used by women, who are allergic to milk protein.			

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1.6	Warnings and cautions	Do not use if you are allergic to milk - contains traces of milk proteins. LadyBalance can be used in cases of dietary lactose intolerance.				
		See your doctor if you have vaginal pain, bleeding or a yellow-green unpleasant smelling discharge - you could have Trichomoniasis.				
		Not recommend if you are also using vaginal products containing bacteria or yeasts (including milk-based products) - this could reduce the effect of LadyBalance or cause adverse effects.				
1.7	Possible bad effects	Clear or gritty discharge (1 in 10 users); light incidents: yeast smell, urge to pass water, headache, itching, spotting (light bleeding) (1 in 100 to 1 in 10 users). These improve after stopping treatment.				
2	Circulated information of product in countries (if any)					
	The product is accepted by the Danish Agency for Medicine based on European Union legislation. The approval is therefore valid for the European Union.					
3	Registered indications in other countries (if any)					
4	Important safety / performance related information					
The requirement to report back any safety events is informed the distribution channel. No significant adverse effects have been reported the 10 years of marketing in Denmark, Europe and other countries in the worl This product does not contain any animal or human cells, cells, tissue or of microbiological or recombinant origin or any irradiation sources.						

LadyBalari

## Legitimate representative of product owner

Signature (Full name and title) Confirm by stamp or digital signature

> INGE DORTHE HANSEN CEO; DEVELOPER



VI LEVIN

This is to certify that **Inge Dorthe Hansen** today in my presence at the Notarial Office approved and signed the above document. No conspicuous corrections or addenda were found in the document.

Inge Dorthe Hansen has proved her identity by showing passport.

The Court in Kolding denmark, 2022-03-08

Charlotte Rytger **Notary Public** 

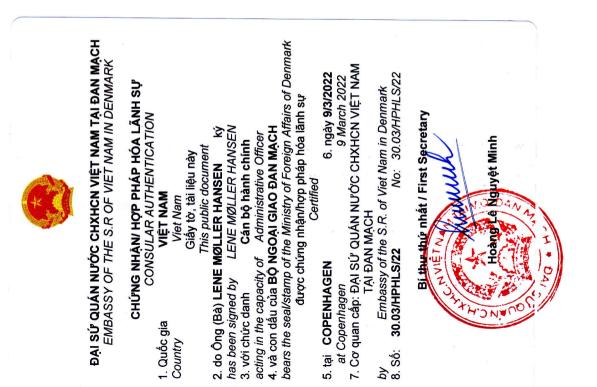


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i	København	den	09 mar 2022				
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