

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### *Tansy 750 microgram tabletten*

Levonorgestrel

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist. .
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

### **For OTC products**

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told to you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This include any possible effect not listed in this leaflet. See section 4.

### **What is in this leaflet:**

1. What Tansy 750 microgram tabletten is and what it is used for
2. What you need to know before you take Tansy 750 microgram tabletten
3. How to take Tansy 750 microgram tabletten
4. Possible side effects
5. How to store Tansy 750 microgram tabletten
6. Content of the pack and other information

**1. What Tansy 750 microgram tabletten is and what it is used for** Tansy 750 microgram tabletten is an emergency contraceptive that can be used within 72 hours (3 days) of unprotected sex or if your usual method of contraception has failed.

When should emergency contraception be used?

- No contraception was used during the sexual intercourse
- The contraception measure was used incorrectly, for example as if a condom was penetrated, slipped away or used in a wrong way, if vaginal pessary or diaphragm changed position, burst, was broken or taken out ahead of time, in the case of a failed interruption during coitus interruptus (e.g. sperm ejaculated in vagina or on external genitalia).

Tansy 750 microgram tabletten contains a synthetic hormone-like substance called levonorgestrel. It prevents about 84% of expected pregnancies when you take it within 72 hours of having unprotected sex. It will not prevent a pregnancy every time and is more effective if you take it as soon as possible after unprotected sex. It is better to take it within 12 hours rather than delay until the third day .

Tansy 750 microgram tabletten is thought to work by:

- stopping your ovaries from releasing an egg;
- preventing sperm from fertilising any egg that may have already released; or
- stopping a fertilised egg from attaching itself to your womb lining .

Tansy 750 microgram tabletten can only prevent you from becoming pregnant if you take it within 72 hours of having unprotected sex. It does not work if you are already pregnant. If another unprotected intercourse takes place after the use of Tansy 750 microgram tabletten (also if this is during the same menstrual cycle), the tablet will not exert its contraceptive effect and there is again the risk of pregnancy.

This product is only for emergency contraception, not for a regular contraception as it is less effective than the regular contraceptive tablet.

Tansy 750 microgram tabletten is not indicated for use before the first menstrual bleeding (menarche).

## **2. What you need to know before you take Tansy 750 microgram tabletten**

### **Do not take Tansy 750 microgram tabletten**

- if you are allergic to levonorgestrel or any of the other ingredients of this medicine (listed in section 6)

### **Warnings and precautions**

If any of the following applies to you, talk to your doctor before taking Tansy 750 microgram tabletten as emergency contraception may not be suitable for you. Your doctor may prescribe another type of emergency contraception for you.

- If you are pregnant or think that you may already be pregnant. This medicine will not work if you are already pregnant. If you are already pregnant, Tansy 750 microgram tabletten cannot terminate pregnancy, so Tansy 750 microgram tabletten is not an “abortion tablet”.

You may already be pregnant if:

- your period is more than 5 days late, or you have experienced unusual bleeding when your next period is due;
- you have had unprotected sex more than 72 hours ago and since your last period.

The use of Tansy 750 microgram tabletten is not advised if:

- you have a disease of your small bowel (such as Crohn’s disease) that inhibits the absorption of the drug ;
- you have severe liver problems;
- you have a history of ectopic pregnancy (where the baby develops somewhere outside the womb)
- you have a history of salpingitis (inflammation of the Fallopian tubes).

Your doctor may decide that Tansy 750 microgram tabletten is not suitable for you, or that another type of emergency contraception would be better for you.

In all women, emergency contraception should be taken as soon as possible after unprotected intercourse. There is some evidence that Tansy 750 microgram tabletten may be less effective with increasing body weight or body mass index (BMI), but these data were limited and inconclusive. Therefore, Tansy 750 microgram tabletten is still recommended for all women regardless of their weight or BMI.

You are advised to speak to a healthcare professional if you are concerned about any problems related to taking emergency contraception.

### **Children and adolescents**

Levonelle-2 is not indicated for use before the first menstrual bleeding (menarche).

### **If you are worried about sexually transmitted diseases**

If you did not use a condom (or if it has been torn or slid down) during the intercourse, it might be possible that you have caught a sexually transmitted disease or the HIV virus. This medicine will not protect you against sexually transmitted diseases, only condoms can do this. Ask your doctor, nurse, family planning clinic or pharmacist for advice if you are worried about this.

### **Other medicines and Tansy 750 microgram tabletten**

Tell your pharmacist or doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription or herbal medicines.

Some medicines may prevent Tansy 750 microgram tabletten from working effectively. If you have used any of the medicines below during the last 4 weeks, Tansy 750 microgram tabletten may be less suitable for you. Your doctor may prescribe another type of (nonhormonal) emergency contraceptive, i.e. a copper intrauterine device (Cu-IUD). If this is not an option for you or if you are unable to see your doctor promptly, you can take a double dose of Tansy 750 microgram tabletten.

- Barbiturates and other medicines used to treat epilepsy (for example, primidone, phenytoin and carbamazepine).
- Medicines used to treat tuberculosis (for example, rifampicin and rifabutin).
- Treatment for HIV (ritonavir, efavirenz).
- A medicine used to treat fungal infections (griseofulvin).
- Herbal remedies containing St. John's Wort (*Hypericum perforatum*).

Speak to your pharmacist or doctor if you need further advice on the correct dose for you.

Consult your doctor as soon as possible after taking the tablets for further advice on a reliable form of regular contraception and to exclude a pregnancy (See section also 3 “How to take Tansy 750 microgram tabletten” for further advice).

Tansy 750 microgram tabletten may also affect how well other medicines work

- A medicine called cyclosporin (suppresses the immune system)

### **How often can Tansy 750 microgram tabletten be used**

You should only use Tansy 750 microgram tabletten in emergencies, and not as a regular method of contraception. If you use Tansy 750 microgram tabletten more than once in a menstrual cycle, it is less reliable and it is more likely to upset your menstrual cycle (period).

Tansy 750 microgram tabletten does not work as well as regular methods of contraception. Your doctor, practice nurse or family planning clinic can tell you about long-term methods of contraception which are more effective in preventing you from getting pregnant.

### **Pregnancy breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

#### *Pregnancy*

You should not take this medicine if you are already pregnant. If you have had unprotected sex which was more than 72 hours ago, and since your last period, you may already be pregnant and the treatment won't work. If your last period was more than 5 days late or was unusually light or unusually heavy, you should check with your doctor that you are not already pregnant .

If you are already pregnant, Tansy 750 microgram tabletten can not break down the pregnancy, Tansy 750 microgram tabletten is thus not an „abortion pill”. If you do become pregnant even after taking this medicine, it is important that you see your doctor. There is no evidence that Tansy 750 microgram tabletten will harm a baby that develops in your uterus/womb if you use Tansy 750 microgram tabletten as described. but there are no clinical data that if you have taken more than two tablets of Levonelle-2 it might harm your baby.

Nevertheless, your doctor may want to check that the pregnancy is not ectopic (where the baby develops somewhere outside the womb). This is especially important if you develop severe abdominal pain after taking Tansy 750 microgram tabletten or if you have previously had an ectopic pregnancy, Fallopian tube surgery or pelvic inflammatory disease.

#### *Breast-feeding*

Very small amounts of the active ingredient of this medicine may appear in your breast milk. This is not thought to be harmful to the baby. However, if you are worried you can take the tablet immediately after a breast-feeding and avoid nursing at least 8 hours following table taking In this way you are taking your tablet well before the next feed and reducing the amount of active ingredient your baby may take in with the breast milk.

#### *Fertility*

Tansy 750 microgram tabletten can alter your menstrual cycle (period) which can sometimes lead to earlier or later ovulation date. These changes can result in modified fertility date, however there are no fertility data in the long term.

### **Driving and using machines**

Tansy 750 microgram tabletten is unlikely to affect your ability to drive a car or use machines. However, if you feel tired or dizzy, do not drive or operate machines.

### **Tansy 750 microgram tabletten contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

### **3. How to take Tansy 750 microgram tabletten**

*Take the two tablets as soon as possible, preferably within 12 hours, and no later than 72 hours (3 days) after you have had unprotected sex. Do not delay taking the tablets. The tablets work best the sooner you take it after having unprotected sex. It can only prevent you becoming pregnant, if you take them within 72 hours of unprotected sex.*

Always use this medicine exactly as described in the leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Tansy 750 microgram tabletten can be taken at any time in your menstrual cycle assuming you are not already pregnant or think you may be pregnant. Do not chew but swallow the tablets whole with water.

- If you are using one of the medicines that may prevent Tansy 750 microgram tabletten from working properly (see section above "Other medicines and Tansy 750 microgram tabletten") or if you have used one of these medicines in the past 4 weeks, Tansy 750 microgram tabletten may work less effectively for you. Your doctor may prescribe another type of (non-hormonal) emergency contraceptive, i.e. a copper intrauterine device (Cu-IUD). If this is not an option for you or if you are unable to see your doctor promptly, you can take a double dose of Tansy 750 microgram tabletten (i.e. 4 tablets taken together at the same time).

- If you are already using a regular method of contraception, such as the contraceptive pill, you can continue to take this at your regular times.

If another unprotected intercourse takes place after the use of Tansy 750 microgram tabletten (also if this is during the same menstrual cycle), the tablet will not exert its contraceptive effect and there is again the risk of pregnancy.

*Neem contact op met uw huisarts indien er meer dan 72 uur is verstreken sinds de onbeschermdde geslachtsgemeenschap. Hij/zij kan ter voorkoming van een zwangerschap een koperhoudend spiraaltje plaatsen (dit kan tot en met de 5e dag na de onbeschermdde geslachtsgemeenschap) of adviseren over andere mogelijkheden.*

Use in children and adolescents

There is no relevant use of <Invented name> in children below the age at which menstruation begins.

#### **What to do if you are sick (vomit)**

If you are sick (vomit) within three hours of taking the tablets, you should immediately take another two tablets.

#### **After you have taken Tansy 750 microgram tabletten**

After you have taken Tansy 750 microgram tabletten, if you want to have sex, and are not using the contraceptive pill, you should use condoms or a cap plus spermicide until your next menstrual period. This is because Tansy 750 microgram tabletten will not work if you have unprotected sex again, before your next period is due.

After taking Tansy 750 microgram tabletten, you are advised to make an appointment to see your doctor about three weeks later to make sure that Tansy 750 microgram tabletten has worked. If your period is more than 5 days late or is unusually light or heavy, you should contact your doctor as soon as possible. If you do become pregnant even after taking this medicine, it is important that you see your doctor.

Your doctor can also tell you about long-term methods of contraception which are more effective in preventing you from getting pregnant.

If you continue to use regular hormonal contraception such as the contraceptive tablet and you do not have a bleed in your tablet-free period, see your doctor to make sure you are not pregnant.

*Als u een van de eerste zeven pillen van de pilstrip bent vergeten in te nemen en het langer dan 36 uur duurt voordat u de volgende pil inneemt, dan bent u een week niet beschermd tegen zwangerschap. Als u in deze week onbeschermd geslachtsgemeenschap hebt, kunt u Tansy 750 microgram tabletten gebruiken.*

*Ondertussen moet u gewoon uw pilstrip afmaken. Om een zwangerschap te voorkomen moet u de eerste 7 dagen nadat u Tansy 750 microgram tabletten heeft ingenomen ook extra voorbehoedsmiddelen gebruiken (condoom of pessarium).*

### **Your next period after you took Tansy 750 microgram tabletten**

After the use of Tansy 750 microgram tabletten, your period is usually normal and will start at the usual day; however sometimes, it will start a few days earlier or later.

If your period starts more than 5 days later than expected, an "abnormal" bleeding occurs at that time or if you think you might be pregnant, you should check whether you are pregnant by pregnancy test.

### **If you take more Tansy 750 microgram tabletten than you should**

Although there have been no reports of serious harmful effects after taking too many tablets at once, you may feel sick, actually be sick (vomit) or have vaginal bleeding.

You should ask your doctor, pharmacist, practice nurse or family planning clinic for advice, especially if you have been sick, as the tablet may not have worked properly.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Possible side effects are listed below according to how common they are:

### **Very common side effects (may affect more than 1 in every 10 users):**

- Feeling sick (nausea)
- You might have some irregular bleeding until your next period
- You might have lower abdominal pain

- Tiredness
- Headache

**Common side effects (may affect up to 1 in 10 users):**

- Being sick (vomiting). If you are sick, read the section "What to do if you are sick (vomit).
- Your period may be different. Most women will have a normal period at the expected time but some may have their period later or earlier than normal. You may also have irregular bleeding or spotting until your next period. If your period is more than 5 days late or is unusually light or heavy, you should contact your doctor as soon as possible.
- You might have tender breasts, diarrhoea or feel dizzy after taking this medicine.

**Very rare side effects (may affect up to 1 in 10,000 users):**

- Rash, urticaria, pruritus, swelling of the face, pelvic pain, painful period.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Nederlands Bijwerken Centrum Lareb, website: [www.lareb.nl](http://www.lareb.nl). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Tansy 750 microgram tabletten**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pack and blister after Exp. The expiry date refers to the last day of the month.

This medicinal product does not require any special storage condition.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information**

**What Tansy 750 microgram tabletten contains**

The active substance is levonorgestrel. Each tablet contains 750 micrograms of levonorgestrel.

The other ingredients are cellulose microcrystalline, lactose monohydrate, poloxamer 188, croscarmellose sodium and magnesium stearate.

**What Tansy 750 microgram tabletten looks like and contents of the pack**

Each pack contains one complete treatment of two round, white tablets, of approximate 6 mm of diameter and marked "C" on one side and "2" on the other.

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder:**

Laboratorios Leon Farma, S.A  
Pol. Ind. Navatejera  
C/ La Vallina s/n, 24008-Navatejera, León.  
Spanje

**Manufacturer:**

Laboratorios Leon Farma, S.A  
Pol. Ind. Navatejera  
C/ La Vallina s/n, 24008-Navatejera, León.  
Spanje

**Marketing authorization number:**

Tansy 750 microgram tabletten is registered under RVG 111881.

**This medicinal product is authorised in the Member States of the EEA under the following names:**

The Netherlands:	Tansy 750 microgram tabletten
Austria	Velafam 0,75mg Tabletten
Bulgaria	Melkidos
Estonia	Elistrel
Germany	Navela 0.75 mg Tabletten
Lithuania	Elistrel 750 mikrogramų tabletės
Latvia	Elistrel 750 mikrogrami tabletes
Spain	Levonorgestrel Exeltis 0.75 mg comprimidos EFG

**Deze bijsluiter is voor het laatst goedgekeurd in februari 2021****9. Overige informatie**

Als u na het lezen van deze bijsluiter nog ergens niet zeker van bent of als u vragen hebt, neem dan contact op met u apotheker of arts of kijk op de website van de Rutger Nisso Groep ([www.rutgersnissogroep.nl](http://www.rutgersnissogroep.nl))

**10. Medisch advies****Informatie over de menstruatiecyclus en voorbehoedsmiddelen (anticonceptie)**

De menstruatiecyclus is de tijd tussen twee menstruaties. Gewoonlijk duurt de cyclus 28 dagen, maar de duur kan van vrouw tot vrouw verschillen.

Een vrouw menstrueert allen wanneer ze niet zwanger is. Tijdens elke cyclus komt een eikel vrij in één van de 2 eierstokken (dit wordt 'eisprong' genoemd). De eisprong vindt gewoonlijk plaats halverwege de cyclus maar kan ook op een ander moment tijdens de cyclus plaatsvinden.

Na de geslachtsgemeenschap kunnen mannelijke zaadcellen (sperma) in de buurt van de eikel komen en de eikel bevruchten (d.w.z. het samengaan van de eikel en een spermacel om zo een embryo te vormen). Na een paar dagen nestelt de bevruchte eikel zich in de baarmoeder en begint de zwangerschap.

Daarom kan een vrouw na geslachtsgemeenschap zwanger worden als tijdens het vrijen geen voorbehoedsmiddel wordt gebruikt.

**Voorbehoedsmiddelen (anticonceptie methoden) werken als volgt:**

- Het voorkomen van de eisprong: dit is het geval met de anticonceptiepil;
- Het voorkomen van de bevruchting (het samengaan van het sperma met de eikel); dit is het geval bij een condoom;
- Het voorkomen van het innestelen van een bevruchte eikel in de baarmoeder: dit is het geval bij de anticonceptiepil en een spiraaltje.

Nood-anticonceptie kan de eisprong of de innesteling van de bevruchte eikel in de baarmoeder blokkeren. Als de innesteling van de bevruchte eikel al is begonnen, dan is Tansy 750 microgram tabletten niet meer werkzaam.