

Package leaflet: Information for the user Tomonil 1.5 mg tablet
levonorgestrel

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

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

What is in this leaflet

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

1. What Tomonil is and what it is used for

Tomonil is an emergency contraceptive that can be used within 72 hours (3 days) of unprotected sex or if your usual contraceptive method has failed.

It can be used in the following cases:

- No contraception was used during intercourse.
- The contraceptive was used incorrectly, e.g., if a condom broke, slipped off or was used incorrectly, if a diaphragm changed position, ruptured, broke or was removed ahead of time, if concerns about failure of interrupted intercourse (e.g., sperm ejaculated in the vagina or on external genitalia).

Tomonil contain a synthetic hormone like active substance called levonorgestrel. It prevents about 84% of expected pregnancies when the tablet is taken within 72 hours (3 days) of having unprotected intercourse. Tomonil will not prevent a pregnancy every time but the tablet is more effective the sooner after unprotected intercourse it is taken. It is better to take it within 12 hours rather than delay until the third day.

Tomonil is thought to work by:

- stopping your ovaries from releasing an egg
- preventing sperm from fertilising an egg you may have already released.

Tomonil can only prevent you becoming pregnant if you take it within 72 hours of unprotected intercourse. It does not work if you are already pregnant. If another unprotected intercourse takes place after the use of Tomonil, the tablet will not exert its contraceptive effect and there is again the risk of pregnancy.

Tomonil is not indicated for use before the first menstrual bleeding.

Levonorgestrel, contained in Tomonil, may also be approved for the treatment of other conditions not mentioned in this product information. Ask your doctor, pharmacist or other healthcare professional if you have any further questions and always follow their instructions.

2. What you need to know before you take Tomonil Do not take Tomonil

- 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 Tomonil as emergency contraception may not be suitable for you. Your doctor may prescribe another type of emergency contraception for you.

- Tell your doctor if you are pregnant or think that you may already be pregnant. Tomonil does not work if you are already pregnant. If you are already pregnant, Tomonil cannot terminate an ongoing pregnancy. Tomonil is therefore not an “abortion pill”.

You may already be pregnant if:

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

The use of Tomonil is not advised if:

- you have a bowel disease (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 inflammation of the fallopian tubes (salpingitis).

A previous ectopic pregnancy and a previous infection of the fallopian tubes increase the risk of a new ectopic pregnancy.

Emergency contraception should be taken as soon as possible after unprotected intercourse. This applies to all women. There is some evidence that Tomonil may be less effective with increasing bodyweight or body mass index (BMI), but these data were limited and inconclusive. Therefore, Tomonil is still recommended for all women regardless of their weight and 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

Tomonil is not indicated for use before the first menstrual bleeding.

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 intercourse, it might be possible that you have caught a sexually transmitted disease or the HIV virus.

Tomonil 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 Tomonil

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription or herbal medicines. Some medicines may prevent Tomonil from working effectively. If you have used any of the medicines below during the last 4 weeks, Tomonil may be less suitable for you. Your doctor may prescribe another type of (non-hormonal) emergency contraceptive, i.e. a copper intrauterine device. 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 Tomonil:

- barbiturates and other medicines used to treat epilepsy (for example, primidone, phenytoin, and carbamazepine)
- medicines used to treat tuberculosis (for example, rifampicin, rifabutin)
- a treatment for HIV (ritonavir, efavirenz)
- a medicine used to treat fungal infections (griseofulvin)
- Traditional herbal remedies containing St John's wort (*Hypericum perforatum*). Talk to your pharmacist or doctor if you need further advice on the correct dose for you.

Consult a 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 also section 3 "How to take Tomonil" for further advice).

Tomonil may also affect how well other medicines work

- a medicine called cyclosporin (suppresses the immune system).

How often can Tomonil be taken

Tomonil should only be used as an emergency measure and not used as a regular method of contraception. If Tomonil is used more than one time during a menstrual cycle, it becomes less reliable and is likely to cause disruption in your menstrual cycle.

Tomonil does not work as well as regular methods of contraception. You can get information from a doctor, reception nurse or contraception clinic about long-term contraceptive methods that prevent pregnancy more effectively.

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 do become pregnant even after taking this medicine, it is important that you see your doctor. There is no evidence that Tomonil will harm a baby if Tomonil is used as directed. Nevertheless, your doctor may want to check that the pregnancy is not ectopic (where the baby develops outside the womb).

This is especially important if you develop severe abdominal pain after taking Tomonil or if you have previously had an ectopic pregnancy, fallopian tube surgery or pelvic inflammatory disease.

Breast-feeding

The active ingredient of this medicine is excreted into your breast milk. Therefore, it is suggested that you take your tablet immediately after a breast-feeding and avoid nursing at least 8 hours after this.

Drain your milk with a breast pump for 8 hours after taking the tablet. 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

Tomonil increases the risk of disturbances in the menstrual cycle, which can sometimes lead to earlier or later ovulation date and thus change the fertile days. There are no long-term data on the fertility but after treatment with Tomonil, a rapid return to fertility is expected. Therefore, regular contraception should be resumed or initiated as soon as possible after use of Tomonil.

Driving and using machines

Tomonil 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 machinery.

You are responsible for assessing whether you are fit to drive a motor vehicle or perform work that requires sharpened concentration. Because of their effects and/or side effects, one of the factors that can affect your ability to do these things is your use of medicines. Description of these effects and side effect can be found in other sections. Read the information in this leaflet for guidance. Talk to your doctor or pharmacist if you are not sure.

Tomonil contains lactose

If you do not tolerate sugar (lactose) you should know that the Tomonil contraceptive pill contains 120 mg lactose monohydrate. If you have an intolerance to some sugars, you should contact your doctor before taking this medicine.

3. How to take Tomonil

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Talk to your doctor or pharmacist if you are not sure.

- Take the tablet as soon as possible, preferably within 12 hours, and no later than 72 hours (3 days) after unprotected intercourse. Do not wait to take the tablet. The tablet works best if you take it as soon as possible after unprotected intercourse. It can only prevent you becoming pregnant if you take it within 72 hours after unprotected intercourse.
- Tomonil 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 tablet whole with

water.

- If you are using one of the medicines that may prevent Tomonil from working properly (see section “Other medicines and Tomonil” above) or if you have used one of these medicines in the past 4 weeks, Tomonil may work less effectively. Your doctor may prescribe another type of (non-hormonal) emergency contraceptive, i.e., a copper intrauterine device. 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 Tomonil (i.e., 2 tablets 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 Tomonil (even if this is during the same menstrual cycle), the tablet will not exert the same contraceptive effect and there is a risk that you could get pregnant.

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

What you should do if you vomit

If you vomit within three hours of taking the tablet, you should immediately take another tablet.

After you have taken Tomonil

If you want to have intercourse after taking Tomonil, and are not using the contraceptive pill, you should use condoms or a diaphragm with spermicide until your next menstrual period. This is because Tomonil will not work if you have unprotected sex again, before your next period is due.

After you have taken Tomonil, you are advised to make an appointment to see your doctor about three weeks later, to make sure that Tomonil have worked. If your period is more than 5 days late or is unusually light or unusually 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.

You can get information from a doctor about long-term contraceptive methods that prevent pregnancy more effectively.

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

Your next period after you took Tomonil

After the use of Tomonil your period is usually normal and will start on the usual day; however sometimes this will be a few days later or earlier. If your menstrual period is delayed by more than 5 days, if abnormal bleeding occurs at the expected date of menstrual period or pregnancy is suspected, pregnancy test should be taken.

If you take more Tomonil than you should

There have been no reports of serious side effects from taking too many tablets at once. If you have taken several tablets at once, you may feel nauseous and vomit, or have vaginal bleeding. You should ask your pharmacist, doctor, practice nurse or family planning clinic for advice, especially if you have vomited, as the tablet may not have worked properly.

If you have taken more medicine than you should or if, for example, a child has taken the medicine, contact your doctor or hospital or Poison information Centre (tel. 112) for risk assessment and advice.

If you have any further questions about this medicine, contact your doctor or pharmacist.

4. Possible side effects

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

Very common (may affect more than 1 in 10 people):

- Nausea
- Irregular bleeding before next period
- Lower abdominal pain
- Fatigue
- Headache

Common (may affect up to 1 in 10 people):

- Vomiting If you are sick, read the section 'What to do if you vomit'
- Your period might 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 might also have some irregular bleeding or spotting until your next period. If your period is more than 5 days late or is unusually light or unusually heavy, you should contact your doctor as soon as possible.
- You might have tender breasts, diarrhoea, feel dizzy after taking this medicine.

Very rare (may affect up to 1 in 10,000 people):

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

Reporting of suspected adverse reactions

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 (see details below) By reporting side effects, you can help provide more information on the safety of this medicine,

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et Box 26

751 03 Uppsala

www.lakemedelsverket.se

5. How to store Tomonil

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

Do not use after the expiry date which is stated on the package after EXP. The expiry date refers to the last day of the month.

No special requirements for storage.

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 to protect the environment.

6. Contents of the pack and other information

The active substance is levonorgestrel. Each tablet contains 1.5 mg of levonorgestrel. The other ingredients are:

Maize starch
Potato starch,
Talc
Silica, colloidal anhydrous
Magnesium stearate E 470 b
Lactose monohydrate

What Tomonil contains

White to off-white round, flat tablets with bevelled edges, debossed with “J06” on one side and plain on the other side

Tomonil is provided in a clear and transparent PVC/aluminium blister containing one tablet. The blister is further packed in a folded carton.

MARKETING AUTHORISATION HOLDER

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