Package leaflet: Information for the user

Monotrim 10 mg/ml Oral Suspension
trimethoprim

Read all of this leaflet carefully before you start taking 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. See section 4.

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

1. What Monotrim suspension is and what it is used for

Monotrim suspension contains trimethoprim which is an antibiotic. It is used to treat certain infections caused by bacteria sensitive to trimethoprim such as:
- Urinary tract infections
- Chest infections.

Trimethoprim may also be given to patients who often suffer from urinary tract infections, to stop the infections from returning.

2. What you need to know before you take Monotrim suspension

Do not take Monotrim suspension:
- if you are allergic to trimethoprim or any of the other ingredients of this medicine (listed in section 6)
- if you are pregnant or planning to become pregnant
- if you have a blood disorder

Do not give Monotrim suspension to very young babies (premature babies or babies less than 6 weeks old).
If any of the above apply to you, speak to your doctor or pharmacist.

Warning and precautions
Talk to your doctor or pharmacist before taking Monotrim suspension:
- if you have a folic acid deficiency
- if you have kidney problems or are having dialysis treatment
- if you have a high concentration of potassium ions in the blood
- if you are elderly

- if you are breast-feeding.

Monotrim suspension can increase potassium blood levels. Patients at risk of increased potassium blood levels include those with kidney problems, poorly controlled diabetes, or those on certain medicines or potassium supplements. The symptoms of severe hyperkalaemia might include muscle cramps, irregular heart rhythm, diarrhoea, nausea, dizziness or headache. Your doctor may perform blood tests to monitor your potassium blood levels.

Other medicines and Monotrim suspension
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may be affected by Monotrim suspension or they may affect how well Monotrim suspension will work.

Tell your doctor or pharmacist if you are taking:

- anticonvulsants for epilepsy or related conditions, particularly phenytoin
- diuretics (water tablets), e.g. bendroflumethiazide, eplerenone, spironolactone, amiloride or triamterene
- medicines likely to increase the amount of potassium in your blood (e.g. potassium supplements, ACE-inhibitors such as lisinopril, angiotensin II antagonists, heparin)
- digoxin, a medicine used to treat certain heart conditions
- medicines to stop the blood clotting or thin the blood (e.g. warfarin)
- ciclosporin, a medicine used to suppress the immune system
- folate antagonists, medicines used to treat rheumatoid arthritis or cancer (e.g. methotrexate or 5-fluorouracil)
- oestrogen-containing contraceptives. Ask your doctor or pharmacist about alternative contraception
- medicines likely to depress bone marrow (e.g. mercaptopurine, azathioprine)
- procainamide, a medicine used to treat certain heart conditions
- repaglinide, a medicine used to treat diabetes
- dapsone, a medicine used to treat skin infections
- pyrimethamie, a medicine used to prevent malaria
- lamivudine, a medicine used to treat HIV
- oral typhoid vaccine, a medicine used to protect against typhoid fever.

Blood monitoring may be carried out if taking these drugs with Monotrim suspension.
If you are unsure whether you are taking any of the above medicines, show the containers of the medicines you are taking to your doctor or pharmacist.

Pregnancy and breast-feeding

Pregnancy
DO NOT take Monotrim suspension if you are pregnant as it may affect your unborn baby.

Breast-feeding
Monotrim suspension can pass into breast milk. Therefore, care should be taken if breast-feeding.

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 this medicine.

Driving and using machines
Monotrim suspension is unlikely to affect your ability to use machinery or to drive.

Monotrim Oral Suspension contains sorbitol, methyl parahydroxybenzoate and sodium

- **sorbitol**
  This medicine contains 2.04 g sorbitol in each 5 ml which is equivalent to 408 mg/ml.
  Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.
  Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- **methyl parahydroxybenzoate**
  This may cause allergic reactions (possibly delayed).
- **sodium**
  This medicine contains less than 1 mmol sodium (23 mg) per ml oral suspension, that is to say essentially 'sodium-free'

3. How to take Monotrim suspension

Always take this medicine exactly as your doctor or pharmacist has told you.
Your doctor will decide on the appropriate dose to suit your condition.
Check with your doctor or pharmacist if you are not sure.
If you suffer from a kidney complaint, your doctor will decide the correct dosage for you.

- Take the suspension by mouth.
- Shake the bottle gently before taking the medicine. It is important to shake up any sediment but do not shake it too hard - it may harm the suspension and produce even more sediment.

The recommended dose is:

Doses to treat urinary or chest infections

Adults and adolescents over 12 years: the usual dose is 20 ml (four 5 ml spoonfuls) twice a day for 7-10 days.

Children under 12 years: the usual dose may be given twice a day for 7-10 days.

Age	**Usual dose given twice a day for 7 to 10 days**
6 weeks to 5 months	2.5 ml (half a 5 ml spoonful)
6 months to 3 years	2.5 ml - 5 ml (half to one 5 ml spoonful)
4 years to 7 years	5 ml - 7.5 ml (one to one-and-a-half 5 ml spoonfuls)
8 years to 12 years	7.5 ml - 12.5 ml (one-and-a-half to two-and-a-half 5 ml spoonfuls)

Your doctor may tell you to double the dose on the first day.

Doses to prevent urinary infections

Adults and adolescents over 12 years: the usual dose is 10 ml (two 5 ml spoonfuls) at night.

Your doctor may tell you to take another 10 ml in the morning as well.
Children under 12 years: your doctor will tell you the correct dose based on the child's weight, to be taken once a day, in the evening.

Elderly
Your doctor may prescribe a lower dose. You will be advised by your doctor.

Taking Monotrim suspension long term
If you are taking this for a long time, blood tests may be carried out. The doctor may also prescribe an additional drug, folic acid, for you to take.

If you take more Monotrim suspension than you should
1. Tell your doctor, pharmacist or nearest hospital casualty department immediately.
2. Take the bottle and any remaining suspension with you so that people can see what you have taken.
3. Do this even if you feel well.

If you forget to take Monotrim suspension
If you suffer from a kidney complaint and you forget to take a dose, ask your doctor or pharmacist for advice. Otherwise, if you forget to take a dose take it as soon as you remember, but if it is almost time for your next dose, skip the missed dose and continue as usual. Do not take a double dose to make up for a forgotten dose.

If you stop taking Monotrim suspension
Do not stop just because you feel better. If you stop too soon, the infection may come back. Keep taking the suspension until the prescribed course is finished.

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. Do not be alarmed by this list of possible side effects. You may not experience any of them.
STOP taking the suspension and **seek medical help immediately** if you have any of the following **allergic reactions:**
- difficulty breathing or swallowing, swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised lumps
- blistering of the mouth, eyes, or genital region, patchy areas of rash, peeling skin, fever or sore throat

Seek immediate medical attention if you have any of the following symptoms:
- eye pain, redness, or sensitivity to bright light, blurred vision, floaters (dots that move across the field of vision)
- sudden headache, stiff neck, fever, sensitivity to bright light, drowsiness and muscle pain, with or without a rash
- unusual bleeding or bruising; repeated infections or infections that will not go away. This may be due to changes in your blood. Blood tests may be carried out to check for this

- yellowing of the skin or whites of the eyes caused by liver or blood problems.

Tell your doctor if you get any of the following side effects:
- muscle pain or muscle weakness
- nausea, vomiting or an upset stomach
- reactions to the sun. Skin may become red, painful and swollen - do not sunbathe, use a sun bed, or expose your skin to UV light.

Some people may get an increased amount of potassium in their blood (especially the elderly or those with kidney problems). You cannot feel or see this, but your doctor may test your blood for this side effect.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance
Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Monotrim suspension

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 bottle, label and on the carton after EXP. The expiry date refers to the last day of that month.
Do not store above 25°C.
Discard any remaining solution 28 days after first opening.
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 Monotrim suspension contains
- The active substance is trimethoprim. Each ml contains 10 mg trimethoprim.
- The other ingredients are carmellose sodium, microcrystalline cellulose, carboxymethylcellulose sodium, ammonium glycyrrhizinate, methyl parahydroxybenzoate (E218), sorbitol (E420), anise oil and purified water. (See end of Section 2 for further information on sorbitol, methyl parahydroxybenzoate and sodium).

What Monotrim suspension looks like and contents of the pack
Monotrim Oral Suspension is a white liquid with an aniseed aroma.
It is available in plastic bottles of 100 ml.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Taw Pharma (Ireland) Ltd, 104 Lower Baggot Street, Dublin 2, D02 Y940, Ireland.

Manufacturer

Delpharm Bladel B.V., Industrieweg 1, 5531 AD Bladel, The Netherlands.

This leaflet was last revised in July 2020.
'Monotrim' is a registered trade mark.