PACKAGE LEAFLET

Package leaflet: Information for the patient

Impugan 10 mg/ml oral drops, solution

furosemide

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

1. What Impugan is and what it is used for

Furosemide acts directly on the kidneys, primarily by increasing the urinary sodium excretion. Consequently more water is excreted and the amount of urine increases. Impugan is a very fast-acting diuretic. The effect is often noticeable as early as 30 minutes after you take a dose. The diuretic effect is dose dependent and reaches maximum after 1-2 hours and last about 4 hours.

Impugan also has a generally mild antihypertensive effect that persists longer than the diuretic effect.

Impugan is used for water retention due to impaired function of e.g. heart, lungs, liver or kidneys and high blood pressure.

2. What you need to know before you take Impugan

Do not take Impugan
- if you are allergic to furosemide or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to substances similar to furosemide, such as some medicines used for diabetes, and to treat infections.
- if you have symptoms of weakness, difficulty in breathing and light-headedness. This could be a sign of having too little water in the body (dehydrated).
- if you have severely impaired liver or kidney function.

Warnings and precautions
Talk to your doctor or pharmacist before taking Impugan:

- If you are elderly, if you are on other medications which can cause a drop in the blood pressure or if you have other medical conditions that could cause a drop in blood pressure.

It is important that you do not make major changes in your eating habits and intake of salts, especially sodium chloride (table salt) (e.g. through fasting), without consulting your doctor.

Furosemide should be given with caution to premature infants due to the the risk of kidney stones.

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

Concomitant treatment with gentamicin (antibiotic) and other similar antibiotics (aminoglycosides) shoud be avoided.
The treatment effect may be affected if Impugan is taken concomitantly with certain other medicines. It applies primarily to heart medication (digitalis, sotalol or ACE inhibitors), painkillers (non-steroidal anti-inflammatory drugs), lithium (used in manic-depressive illness) or other blood pressure lowering medicines (e.g. aliskiren). The doctor handling the treatment needs to be aware of such concomitant medication.

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 this medicine.

Pregnancy
There is a risk that the fetus gets affected. Ask your doctor before using Impugan during pregnancy.

Breast-feeding
It is possible that breast-fed babies may be affected. Do not use Impugan during lactation unless specifically prescribed by your doctor. Nursing mothers should be aware of that the amount of milk may decrease.

Driving and using machines
No known effect on the ability to drive or perform precision work.

Impugan contains ethanol
This medicine contains 94 mg of alcohol (ethanol) in each ml. The amount in 4 ml of this medicine (normal adult dose) is equivalent to less than 10 ml beer or 4 ml wine.
The small amount of alcohol in this medicine will not have any noticeable effects.

Impugan contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per 24 ml, that is to say essentially ‘sodium-free’.

3. How to take Impugan

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The dose is determined by the doctor, who will adjust it individually for you.

The recommended adult dose for oedema or hypertension is: 20-80 mg per day.

The recommended dose for children is: 1-3 mg/kg body weight per day.

The drops may be mixed with lukewarm tea or cold milk, but acidic beverages such as fruit juice should be avoided.

If you take more Impugan than you should
If you accidentally take more Impugan than you should you must contact your doctor, the hospital or the poison control center.

Possible signs of overdose include dizziness and fainting as well as uncomfortable side effects. See below.

4. Possible side effects

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

Stop taking Impugan and see a doctor straight away if you notice any of the following serious side effects:

Rare: (may affect up to 1 in 1,000 people)
- Impugan may affect the white blood cells leading to decreased defence against infection. If you experience an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems, you should see a doctor to do blood tests so that to rule out a lack of white blood cells (agranulocytosis). It is important that you give information about your medication.
- Intense skin rash including hives, severe itching, blistering, peeling and swelling of the skin and inflammation of mucous membranes may occure or blistering and peeling of the top layer of the skin (Stevens-Johnson syndrome, Toxic epidermal necrolysis).

Not known: (cannot be estimated from the available data)
- A red, scaly widespread rash with bumps under the skin and blisters mainly localised on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised anthematous pustulosis).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

The following side effects have also been reported:

Very common: (may affect more than 1 in 10 people)
- Kidney stones in infants.

Common: (may affect up to 1 in 10 people)
- Decreased blood potassium levels, which can appear in the form of muscle weakness.
- Decreased blood levels of e.g. sodium, magnesium, chloride and calcium.
- Elevated levels of uric acid in the blood.
- Decreased blood volume due to the decreased amount of fluid in the tissues. This is the case when treated with high doses and for a prolonged period of time.

Uncommon: (may affect up to 1 in 100 people)
- Nausea and vomiting.
- Low blood pressure.
- Severe reduction in blood cells which can cause weakness, bruising or make infections more likely (aplastic anaemia).
- Dehydration.
- Deafness (sometimes irreversible)

Rare: (may affect up to 1 in 1,000 people)
- Reduction in blood platelets, which increases risk of bleeding and bruising.
- Severe reduction in the number of white blood cells, which makes infections more likely.
- Inflammation of blood vessels, often with skin rash or red to purple skin discolourations.
- Liver reactions causing changes in blood tests.
- Rash, itching, red to purple skin discolourations.
- Red, scaly patches of skin, loss of hair or loosening of nails (called ‘exfoliative dermatitis’).
- Circular, irregular red patches on the skin of the hands and arms (erythema multiforme).
- Skin reactions associated with sunlight.

- Elevated blood sugar levels.
- When treated with very high doses, tinnitus and temporary hearing loss can occur.

Not known: (cannot be estimated from the available data)
- Inflammation of the pancreas that may cause severe pain in the stomach and back.
- Worsening of kidney dysfunction and inflammation.
- Liver damage.
- Dizziness, fainting and loss of consciousness (caused by symptomatic hypotension).

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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Impugan

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 carton and the bottle. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Impugan contains

- The active substance is furosemide. Each ml of Impugan contains 10 mg of furosemide.
- *The other ingredients are*: sodium saccharin, sodium hydroxide, ethanol 96 % (V/V) and water.

What Impugan looks like and contents of the pack

What Impugan looks like:
The oral drops are a colourless or pale yellowish solution.

Packsize:
Bottle with graduated dose pipette, 30 ml.

Marketing Authorisation Holder and Manufacturer
[To be completed nationally]

Manufacturer
Balkanpharma Troyan AD
1 Krayrechna Str
BG-5600 Troyan
Bulgaria

This leaflet was last revised in 2024-07-12.