

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Iraksin 5, 10 and 20 microgram Tablets Liothyronine sodium

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 Iraksin Tablets are and what they are used for
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1. What Iraksin Tablets are and what they are used for

Iraksin Tablets are a form of thyroxine which is quick acting and long lasting. Thyroxine is a hormone produced by the thyroid gland in the neck which controls many body functions. Iraksin Tablets are used to:-

- treat some of the more severe conditions in which the thyroid does not produce enough thyroxine,
- balance the effect of medicines used to treat an overactive thyroid.

2. What you need to know before you take Iraksin Tablets

Do not take Iraksin Tablets:

- if you are allergic to liothyronine sodium or any of the other ingredients of this medicine (listed in section 6 at the end of this leaflet),
- if you have angina (chest pain when exercising) or conditions affecting your heart or circulation,
- if you are suffering from thyrotoxicosis (condition due to over activity of the thyroid gland).

Warnings and precautions:

Talk to your doctor or pharmacist before taking Iraksin Tablets if:

- you are suffering from diabetes. Iraksin Tablets may raise blood sugar levels,
- you are suffering from a condition called myxoedema (which can happen when you have a problem with your thyroid gland) which makes your skin look swollen and dry,
- you are elderly,
- you have suffered from low levels of thyroid hormone in your body for a long time, as this may affect how your adrenal glands work. You may be given additional medication (corticosteroids) if this is the case,
- you are suffering from any heart problems,
- you are having increased blood pressure,
- you suffer from increased heart rate, sleeplessness, loose watery stools (suggesting increased metabolism) on initiation of treatment. In this case dose reduction would be required,
- you are initiating treatment, as an ECG test done at that time would be valuable,
- if you are pregnant or breast-feeding
- if you are about to undergo laboratory testing for monitoring your thyroid hormone levels, you must inform your doctor and/or the laboratory personnel that you are taking or have recently taken biotin (also known as vitamin H, vitamin B7 or vitamin B8). Biotin may affect results of your laboratory tests. Depending on the test, the results may be falsely high or falsely low due to biotin. Your doctor may ask you to stop taking biotin before performing laboratory tests. You should also be aware that other products that you may take, such as multivitamins or supplements for hair, skin, and nails could also contain biotin. This could affect the results of laboratory tests. Please inform your doctor and/or the laboratory personnel, if you are taking such products (see section Other medicines and Iraksin Tablets).

Children and adolescents:

For more information, talk to your doctor.

Other medicines and Iraksin Tablets:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Iraksin Tablets may affect or be affected by the following medicines:

- anticoagulants (e.g. warfarin) used to thin the blood and prevent blood clots,
- anticonvulsants (e.g. carbamazepine or phenytoin) used to prevent fits,
- insulin and other treatments for diabetes,
- medicines called cardiac glycosides (e.g. digoxin) used to treat heart conditions such as heart failure,
- tricyclic antidepressants (e.g. amitriptyline / imipramine) used to treat depression,
- colestyramine / colestipol which reduces the level of cholesterol (fats) in the blood,
- oral contraceptives ('The Pill'),
- amiodarone, used to treat irregular heart beats,
- barbiturates, used to induce sleep and decrease anxiety,
- primidone, used for seizures or fits.

If you are taking or have recently taken biotin, you must inform your doctor and/or the laboratory personnel when you are about to undergo laboratory testing for monitoring your thyroid hormone levels. Biotin may affect results of your laboratory tests (see section Warnings and precautions).

Pregnancy and 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.

The decision on whether it is best to take Iraksin Tablets during pregnancy or breast-feeding will be made by your doctor.

Driving and using machines

This medicine should not interfere with your ability to drive or use machinery.

Iraksin Tablets contains lactose

This medicine contains lactose, which is a sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Important information about Iraksin Tablets

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

3. How to take Iraksin Tablets

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

Iraksin Tablets are taken by mouth. You should swallow a whole tablet with a glass of water.

If you have any difficulty in swallowing a whole tablet, then you may crush the tablet and add it to a glass with minimum of 20 ml of water and swirl for 5 minutes until completely dissolved. Please ensure that you take the entire amount of water to ensure you take the full dose. Do not worry if the solution appears cloudy. If you are unsure how to take the medicine correctly, check with your doctor or pharmacist.

The recommended dose is as follows:

Adults:

The dose will depend upon your condition, ranging from 10 micrograms to 60 micrograms daily in divided doses.

Use in Children and adolescents:

Children below 12 years of age:

The dose may be started at 5 micrograms a day.

Adolescents (Children 12 -17 years of age):

Initially 10 - 20 micrograms daily; increased to 60 micrograms daily in 2-3 divided doses.

Elderly:

The dose may be started at 5 micrograms a day.

Please note that your doctor will monitor your thyroid function regularly to make sure that you are given the right dose for your condition.

If you take more Iraksin Tablets than you should

Contact your doctor or nearest hospital casualty department as soon as possible. Take any remaining tablets and this leaflet with you so the medical staff will know what you have taken. This may cause agitation, confusion, headache, sweating and a rapid pulse.

If you forget to take Iraksin Tablets

Do not take a double dose to make up for a forgotten tablet or dose. Take the next dose at the correct time and then go on as before. It is important, in order for your medicine to work, that doses are not forgotten.

If you stop taking Iraksin Tablets

Do not stop taking Iraksin Tablets unless your doctor tells you to.

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. Side effects you could experience are:

Not known (frequency cannot be estimated from available data):

- Vomiting (being sick),
- Insomnia (sleeplessness),
- Fever,
- Intolerance to heat,
- Tremor (involuntary, rhythmic muscle movements),
- Allergic reactions such as rash, itching, oedema (abnormal accumulation of body fluid),
- Angina pain (pain in the chest when exercising),
- Irregular, thumping or fast heart beats,
- Muscle cramps or weakness,
- Diarrhoea,
- Restlessness or excitability,
- Headache, face and neck redness, sweating,
- Loss of weight.

Additional side effects seen in children

- Temporary loss of hair in children

These effects normally mean the dose of the medicine needs changing. You should consult your doctor, if these effects occur. The effects usually go away when the dose has been changed.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Iraksin Tablets

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

Do not store above 25°C. Store in the original package to protect from light.

Do not use this medicine after the expiry date which is stated on the carton or blister after 'EXP'. The expiry date refers to the last day of that month.

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 Iraksin Tablets contain:

- The active substance is liothyronine sodium. Each tablet contains either 5 micrograms or 10 micrograms or 20 micrograms liothyronine sodium.
- The other excipients are: lactose monohydrate, partially pregelatinized maize starch, spray dried acacia, sodium chloride and magnesium stearate.

What Iraksin Tablets look like and contents of the pack:

Iraksin 5 microgram Tablets: white to off white, circular biconvex tablets, plain on one side and debossed with “L1” on the other side, 5.5 mm diameter.

Iraksin 10 microgram Tablets: white to off white, circular biconvex tablets, plain on one side and debossed with “L2” on the other side, 5.5 mm diameter.

Iraksin 20 microgram Tablets: white to off white, circular biconvex tablets, plain on one side and debossed with “T3” on the other side, 5.5 mm diameter.

Iraksin 5, 10 and 20 microgram Tablets are available in blister packs of 7, 10, 14, 20, 28, 30, 56, 60, 84, 90 and 112 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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