

SKELID® Tablets

Tiludronate Disodium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SKELID Tablets.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this information with the tablets.

You may wish to read it again later.

What SKELID is used for

SKELID is used to treat Paget's disease of the bone. Normally, bone is continually being built up, removed and replaced. In Paget's disease this process happens too quickly and the new bone produced is weaker than normal. The affected bone may become enlarged and can be painful. SKELID controls this process.

Before you take SKELID

When you must not take it

Do not use SKELID if you are allergic to medicines similar to SKELID (these medicines are called bisphosphonates), or to any of the other ingredients listed under Product Description at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching, difficulty breathing, swelling of the face, lips or tongue.

If you are not sure if you have taken these types of medicines your doctor or pharmacist will be able to help you.

Tell your doctor if you are planning to have dental treatment. You may need to have any dental treatment completed before starting SKELID.

Do not take SKELID if you are pregnant or planning to become pregnant.

The safety of SKELID in pregnancy is not known.

Do not take SKELID if you are breast-feeding.

It is not known whether SKELID passes into the breast milk.

Do not take SKELID if you have severe kidney disease.

SKELID is not suitable for children.

Do not take SKELID after the expiry date (EXP) printed on the carton.

If you take SKELID after the expiry date it may not work as well.

Do not take SKELID if the carton is damaged or shows signs of tampering or the tablets do not look quite right.

Before you start to take it

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- pain, swelling or numbness of the jaw or a heavy jaw feeling or loosening of a tooth
- if you have dental or jaw-bone problems or are planning to have dental treatment.

Tell your doctor if you have any form of kidney disease.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may affect the way SKELID works. These include:

- calcium, mineral or vitamin supplements
- medicines which are used for heartburn, indigestion or stomach ulcers. These include antacids and other treatments which your doctor may have prescribed for you. If you are unsure about the suitability of these types of medicines you should check with your doctor
- indomethacin.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines or if you are not sure about whether other medicines you are taking should not be taken with SKELID.

If you have not told your doctor about any of these things, tell him or her before you take any SKELID.

How to take SKELID

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ to the information contained in this leaflet.

If you do not understand the instructions on the carton, ask your doctor or pharmacist for help.

The usual dose of SKELID is 2 tablets taken once a day.

The tablets should be swallowed whole and taken with a glass of water. Do not chew or suck the tablet.

Take your SKELID Tablets at least 2 hours after a meal.

Do not eat two hours before taking SKELID or for another two hours after taking the tablets.

It is important to avoid milk, dairy products or other foods with a high calcium content within this four hour period.

Do not take indigestion or ulcer remedies containing calcium, magnesium or aluminium during this period.

SKELID is not usually given for more than 3 months at a time. However, treatment for longer than this time may be prescribed by your doctor. If you have been taking SKELID continuously for more than three months you should discuss this with your doctor.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablet(s) as you would normally.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26), or go to the accident and emergency department at your nearest hospital, if you think you or anyone else may have taken too much SKELID. Do this even if there are no signs of discomfort or poisoning.

While you are taking SKELID

Things you must do

If you become pregnant while you are taking SKELID, tell your doctor.

If you are about to take any new medicines, tell your doctor and pharmacist that you are taking SKELID.

Tell all doctors, dentists and pharmacists who are treating you that you are taking SKELID.

If you develop a toothache or require a dental procedure tell your dentist that you are taking SKELID.

Things you must not do

Do not give SKELID to anyone else, even if they have the same condition as you.

Do not let yourself run out of medicine over the weekend or on holidays.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while taking SKELID.

SKELID helps most people with Paget's disease but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor, dentist or pharmacist if you notice:

- jaw-bone or dental problems (including toothache)
- jaw-bone problems, which may include delayed healing and infection after tooth extraction or other work that involves drilling into the jaw.

These side effects are rare but maybe serious.

Tell your doctor if you notice any of the following symptoms and they worry you:

Stomach problems such as:

- nausea
- loose bowels (or diarrhoea)
- stomach (or abdominal) pain.

Other problems such as:

- headache
- dizziness
- weakness
- skin rash
- unusual fracture of the thigh bone may occur rarely, particularly in patients on long-term treatment for osteoporosis. Contact your doctor if you experience pain, weakness or discomfort in your thigh, hip or groin as this may be an early indication of a possible fracture of the thigh bone.

Other side effects not listed above may also occur in some patients.

Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking SKELID

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the pack they will not keep well.

Keep your SKELID Tablets in a cool dry place where the temperature stays below 30°C.

Do not store SKELID Tablets or any other medicines in the bathroom or near a sink.

Do not leave SKELID in the car on hot days. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking the SKELID Tablets or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

SKELID are round white tablets, which are available in cartons containing 56 tablets.

Ingredients

Active ingredients:

each SKELID tablet contains the medicine tiludronate disodium, equivalent to tiludronic acid 200 mg.

Other ingredients:

- lactose
- sodium lauryl sulphate
- crospovidone
- hypromellose
- magnesium stearate

SKELID tablets do not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Sanofi-Aventis Australia Pty Ltd

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Macquarie Park NSW 2113

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