

Budesonide Te Arai

Budesonide

3 mg, Controlled-Release Capsules

What is in this leaflet

Please read this leaflet carefully before you start using Budesonide Te Arai.

This leaflet answers some common questions about Budesonide Te Arai. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Budesonide Te Arai against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What Budesonide Te Arai is used for

Budesonide is used to treat Crohn's disease. It can be used to treat acute attacks. Crohn's disease is an inflammatory disease of the bowel. It mainly affects the small bowel and the first part of the large bowel and causes symptoms such as stomach pain, diarrhoea and fever.

Budesonide Te Arai contains budesonide. It belongs to the group of medicines called corticosteroids, which are used to help reduce inflammation in many parts of the body. Budesonide capsules are designed to release their contents gradually in the last part of the small bowel (the ileum) and the first part of the large bowel.

Ask your doctor if you have any questions about why budesonide has been prescribed for you.

Your doctor may have prescribed budesonide for another reason.

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This medicine is available only with a doctor's prescription.

This medicine is not addictive.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Before you use Budesonide Te Arai

When you must not use it

Do not use budesonide if you have an allergy to:

- any medicine containing budesonide
- any ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- rash, itching or hives on the skin
- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, or other parts of the body.

Do not give Budesonide Te Arai to children. There is only limited information available about the use of budesonide in children.

Do not take this medicine after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Before you start to use it

You must tell your doctor if you have any allergies to any other medicines, foods preservatives or dyes.

Tell your doctor if you have or have had any medical condition, especially the following:

- any recent infection (including chicken pox and measles)
- tuberculosis
- diabetes
- liver disease
- stomach ulcers

- brittle bones (osteoporosis)
- high blood pressure
- eye problems (such as glaucoma or cataracts)

It may not be safe for you to take budesonide if you have any of these conditions.

Tell your doctor if you have NOT had chicken pox or measles. These diseases may be more serious if you get them while taking budesonide. Your doctor may want to vaccinate you for them before you start on budesonide.

Do not take budesonide if you are pregnant, think you might be pregnant or are breastfeeding unless your doctor says to do so. Ask your doctor about the risks and benefits involved. There is very limited experience with budesonide in pregnant or breastfeeding women.

Contains Sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

If you have not told your doctor about any of the above, tell them before you start using Budesonide Te Arai.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking budesonide.

Some medicines may interfere with budesonide. These include:

- other corticosteroid medicines such as tablets, asthma inhalers, nasal sprays, eye/nose drops
- medicines used to treat fungal infections (e.g. ketoconazole)
- cimetidine, a medicine used to treat reflux and stomach ulcers
- Some medicines may increase the effects of budesonide capsules and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

These medicines may be affected by budesonide or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking budesonide.

Diagnostic tests for pituitary glands activity may show false low values due to suppression of the adrenal function.

How to take Budesonide Te Arai

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

How much to take

The usual dose is 3 capsules taken once daily in the morning, before breakfast. Swallow budesonide capsules whole with a glass of water. Do not crush or chew the capsules. If the granules are chewed or crushed, they won't work properly. Talk to your doctor or pharmacist if you have difficulties swallowing the capsules.

How long to take it

Continue taking budesonide for as long as your doctor tells you.

A treatment course is usually 8 weeks.

It may take 2-4 weeks to get the full effect from budesonide. Do not forget to take it even if you feel better. Treatment with budesonide must not be stopped suddenly.

The dose needs to be reduced over the last 2-4 weeks.

If you forget to take it

If you miss a dose, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

While you are using Budesonide Te Arai

Things you must do

Take Budesonide Te Arai exactly as your doctor has prescribed.

If you have not had chicken pox or measles, avoid close contact with anyone who has these diseases while you are taking budesonide. Tell your doctor straight away if you think that you have been exposed to chicken pox or measles.

Tell your doctor if you have an infection while you are taking budesonide. It may not be safe for you to continue taking budesonide if you have an infection.

If you are about to be started on any new medicine, remind your doctor or pharmacist that you are taking budesonide capsules. Tell any other doctors, dentists and pharmacists who are treating you that you are taking budesonide.

If you become pregnant while using budesonide, tell your doctor or pharmacist immediately.

Things you must not do

Do not take budesonide with grapefruit or grapefruit juice. Grapefruit juice, but not other fruit juices, can affect budesonide levels in the body. This may increase the chance of getting unwanted side effects.

Do not stop taking budesonide unless your doctor tells you to. You need to reduce the dose gradually before stopping. Your doctor will tell you how to do this.

Do not use budesonide to treat any other complaints unless your doctor tells you to.

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

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital if you think that you or anyone else may have taken too much budesonide.

Do this even if there are no signs of discomfort or poisoning.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Budesonide Te Arai.

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 adverse effects. Ask your doctor or pharmacist to answer any questions you may have.

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

- indigestion, flatulence
- rapid heart rate or palpitations
- swelling / rounding of the face, acne, weight gain and bruising more easily
- muscle cramps muscle weakness (may be due to low levels of potassium in blood)
- tiredness
- trouble sleeping

- tremor, feeling nervous
- mood swings
- depression, anxiety or aggression
- shaking, muscle spasms or twitching
- menstrual problems
- skin rash, itchiness, or discolouration

These side effects are usually mild.

If your medicine has been changed from other oral corticosteroids (e.g. prednisolone, prednisolone or methylprednisolone) to budesonide capsules, you may notice symptoms such as rash, or pain in muscles and joints. If this happens or you get headaches, feel sick, vomit, or feel tired please contact your doctor.

Tell your doctor or pharmacist if you notice any of the following:

- sign or symptoms of an infection
- blurred vision or other visual disturbances.

These may be serious side effects. You may need medical attention.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, or other parts of the body
- severe rash

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor if you notice anything else that is making you feel unwell. Some people may get other side effects while taking budesonide.

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

If you have changed from or used high doses of oral corticosteroids over a long period of time, your adrenal glands may be affected. Your doctor may do tests to check how the adrenal glands are working.

Your doctor may also tell you to take additional oral corticosteroids during periods of stress such as trauma and surgery.

A slowing of the rate of growth maybe observed if Entocort is used in children and adolescents.

Ask your doctor to answer any questions you may have.

After using Budesonide Te Arai

Storage

Keep your capsules in the bottle until it is time to take them. Replace the cap firmly after use.

If you take Budesonide Te Arai out of the bottle it will not keep well. Keep the capsules in a cool dry place where the temperature stays below 25°C. Do not store Budesonide Te Arai or any other medicine in the bathroom or near a sink. Heat and dampness can destroy some medicines.

Keep Budesonide Te Arai where young 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

Ask your pharmacist what to do with any capsules you have left over if your doctor tells you to stop taking them, or you find that they have expired.

Product description

What it looks like

Budesonide Te Arai is a hard gelatin capsules, light grey opaque body and swedish orange opaque cap.

Ingredients

Active ingredient:

- 3 mg of Budesonide

Inactive ingredients:

Capsule content

- Sugar pellets 071-0.85 (Maize starch & Sucrose)
- Ethyl cellulose Dispersion Type B
- Polysorbate 80
- Methacrylic acid polymer type C
- Triethyl citrate
- Talc

Capsule shell

- Black iron oxide E172
- Red Iron Oxide E172
- Titanium dioxide E171
- Gelatin

Contains Sucrose.

Sponsor Details

Budesonide Te Arai is supplied in New Zealand by:

Te Arai BioFarma Ltd.

PO Box 46205
Herne Bay
Auckland
NEW ZEALAND

0800 832 724

Date of Preparation

This leaflet was prepared on 20 July 2023.