Budesonide tablets, capsules and granules (Budenofalk, Entocort CR, Cortiment)

Budesonide belongs to a class of medicines known as corticosteroids (more commonly called steroids).

Your pharmacist will give you a blue steroid treatment card. Carry this with you at all times.

If you come into contact with anyone who has measles, shingles or chickenpox (or who suspects they may have one of these viruses) you must see your doctor as soon as possible.

About budesonide

<table>
<thead>
<tr>
<th>Type of medicine</th>
<th>A corticosteroid, also commonly called an oral steroid</th>
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<tr>
<td>Used for</td>
<td>Inflammatory bowel disease such as Crohn's disease or ulcerative colitis; chronic diarrhoea due to collagenous colitis; autoimmune hepatitis</td>
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<tr>
<td>Also called</td>
<td>Budenofalk®; Entocort® CR; Cortiment®</td>
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<tr>
<td>Available as</td>
<td>Capsules, modified-release capsules, modified-release tablets, and granules</td>
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Budesonide works by reducing inflammation, and this eases the symptoms of flare-ups of inflammatory bowel conditions.

**Crohn's disease** is a condition which causes inflammation in the gastrointestinal system. Any part of the system can be affected, although the most common site for the disease to start is the lower part of the small intestine, called the ileum. Other parts of the small intestine and the colon are also commonly affected. When the disease flares up, the inflammation causes varying symptoms depending on which part of the gastrointestinal system is affected. Common symptoms are pain, diarrhoea, weight loss and ulcers.

Ulcerative colitis causes inflammation of the large intestine, which leads to problems such as ulceration and bleeding. This causes symptoms such as tummy (abdominal) pain and diarrhoea.

A brand of budesonide called Budenofalk® is used to treat some other conditions associated with inflammation too. It is a treatment for a type of chronic liver inflammation known as **autoimmune hepatitis**, and it also reduces diarrhoea caused by a chronic inflammatory condition of the large bowel (called collagenous colitis).

There are a number of different budesonide preparations and brands. The way the manufacturers make each of these differs slightly; this allows the different brands to release budesonide in specific areas of the intestine. You will be prescribed the brand that allows budesonide to be released in the part of your intestine which requires it most.
Before taking budesonide

Some medicines are not suitable for people with certain conditions, and sometimes a medicine can only be used if extra care is taken. For these reasons, before you start taking budesonide it is important that your doctor knows:

- If you are pregnant or breast-feeding (even though budesonide could still be prescribed for you).
- If you have any kind of infection, or if you have ever had tuberculosis (TB).
- If you have had a heart attack, or if you have a heart condition.
- If you have any problems with the way your liver works, or if you have any problems with the way your kidneys work.
- If you have sugar diabetes, or if you have an eye condition called glaucoma. You should also tell your doctor if a close member of your family has either of these conditions.
- If you have ever had any of the following conditions: high blood pressure, osteoporosis, diverticulitis, an underactive thyroid, epilepsy, cataracts, or a condition causing severe muscle weakness (called myasthenia gravis).
- If you have ever had any of the following: a blood clot in a blood vessel, a stomach ulcer, or a mental health problem such as depression or psychosis.
- If you are taking any other medicines. This includes any medicines which are available to buy without a prescription, as well as herbal and complementary medicines.
- If you have ever had an allergic reaction to a medicine, or if you have ever developed muscle pain after taking a steroid medicine.

How to take budesonide

- Before you start the treatment, read the manufacturer’s printed information leaflet from inside the pack. It will give you more information about budesonide, and will also provide you with a full list of the side-effects which you could experience from taking it.
- Your doctor will tell you how to take budesonide and this information will also be printed on the label of the pack to remind you about what the doctor said to you. It is important that you take your doses exactly as your doctor tells you to. The following doses are intended as a guide only:
  - If you have been given Budenofalk® capsules, the usual dose is one capsule three times daily, 30-60 minutes before a meal, or alternatively, three capsules taken together in the morning before breakfast.
  - If you have been given Entocort® capsules, the usual dose is three capsules taken together in the morning, preferably before breakfast. Swallow the capsules with a drink of water.
  - Budenofalk® granules are taken as a single dose of one sachet in the morning, 30-60 minutes before breakfast. Place the granules on your tongue and swallow them with a drink of water. Do not chew the granules as you swallow.
  - If you have been given Cortiment® tablets, the usual dose is one tablet in the morning. Swallow the tablet with a drink of water. It can be taken with or without food.

- Do not take antacids or indigestion remedies during the two hours before and the two hours after you take budesonide. This is because antacids could affect the way the medicine is released and could stop it from getting to the correct part of your bowel.
- Try to take your doses at the same time(s) of day each day. Doing this will help you to remember to take budesonide regularly. If you do forget to take a dose, take it as soon as you remember (unless it is nearly time for your next dose, in which case leave out the missed dose). Do not take two doses together to make up for a forgotten dose.
- Continue to take budesonide until your doctor tells you to stop. It is usual to be prescribed a course of treatment that lasts for up to eight weeks. Your doctor may ask you to reduce your dose gradually during the last couple of weeks of the course.

Getting the most from your treatment

- You will be given a 'steroid treatment card' which says that you are on steroids and which contains some important advice for you. It is important that you read this card and carry it with you while you are taking budesonide. It contains details about your dose, how long you have been taking a steroid for, and who prescribed it for you. Please make sure that this information is kept up to date. If you are having an operation or any medical treatment, please tell the person carrying out the treatment that you are taking budesonide and show them your treatment card.
Try to keep your regular appointments with your doctor. This is so your doctor can check on your progress. You may need to have some blood tests from time to time.

Budesonide can suppress your immune system, so it is important if you become ill that you make an appointment to see your doctor straightaway. Also, if you come into contact with anyone who has measles, shingles or chickenpox (or who suspects they may have one of these viruses), you must see your doctor as soon as possible.

It is recommended that you do not drink grapefruit juice while you are on budesonide. This is because a chemical in grapefruit increases the amount of budesonide in your bloodstream. This makes side-effects more likely.

If you buy any medicines, check with a pharmacist that they are suitable to take with budesonide.

Some vaccines may not be suitable for you while you are being treated with budesonide. If you need any immunisations, make sure you mention that you are taking a steroid medicine.

Do not stop taking budesonide without speaking with your doctor first. This is particularly important if you have been taking budesonide for more than three weeks. Your doctor will want you to reduce your dose gradually when this is necessary, as stopping suddenly can lead to problems.

Can budesonide cause problems?

Along with its useful effects, budesonide can cause unwanted side-effects which your doctor will discuss with you. The benefits of taking budesonide usually outweigh the side-effects; however, they can sometimes be troublesome. Although not everyone experiences side-effects, and some will improve as your body adjusts to the new medicine, speak with your doctor or pharmacist if you become concerned about any of the following:

<table>
<thead>
<tr>
<th>Common budesonide side-effects</th>
<th>What can I do if I experience this?</th>
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<tbody>
<tr>
<td>Tummy (abdominal) pain, feeling sick, indigestion</td>
<td>Stick to simple or bland foods - avoid fatty or spicy foods</td>
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<tr>
<td>Changes in behaviour or mood</td>
<td>If you become anxious, confused, or start having worrying thoughts about harming yourself, speak with your doctor as soon as possible</td>
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<tr>
<td>Feeling tired</td>
<td>If this becomes troublesome, speak with your doctor</td>
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<tr>
<td>Headache</td>
<td>Ask your pharmacist to recommend a suitable painkiller</td>
</tr>
<tr>
<td>Cold or flu-like symptoms, other infections</td>
<td>Speak with your doctor about this, especially if you have been in contact with someone with chickenpox, measles or shingles</td>
</tr>
<tr>
<td>Blurred eyesight, muscle cramps, itchy skin rash, heavy or irregular periods, the sensation of having a ‘thumping heart’ (palpitations), problems sleeping (insomnia)</td>
<td>If any of these become troublesome, speak with your doctor</td>
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For more information about side-effects which can develop when steroids are taken longer-term, please see the separate leaflet called Oral Steroids.

If you experience any other symptoms which you think may be due to budesonide, speak with your doctor or pharmacist for further advice.

How to store budesonide

- Keep all medicines out of the reach and sight of children.
- Store in a cool, dry place, away from direct heat and light.
Important information about all medicines

Never take more than the prescribed dose. If you suspect that you or someone else might have taken an overdose of this medicine, go to the accident and emergency department of your local hospital at once. Take the container with you, even if it is empty.

This medicine is for you. Never give it to other people even if their condition appears to be the same as yours.

Do not keep out-of-date or unwanted medicines. Take them to your local pharmacy which will dispose of them for you.

If you have any questions about this medicine ask your pharmacist.

Further reading & references

- Manufacturer's PIL, Budenofalk® 3 mg gastro-resistant capsules; Dr. Falk Pharma UK Ltd, The electronic Medicines Compendium. Dated February 2015.
- Manufacturer's PIL, Budenofalk® 9 mg gastro-resistant granules; Dr. Falk Pharma UK Ltd, The electronic Medicines Compendium. Dated August 2013.

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