

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Iscover®. It does not contain all the available information. Some of the information it contains may not apply to you. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. In deciding to give you Iscover, your doctor has weighed the risks of you taking Iscover against the benefits it will have for you.

Always follow the instructions that your doctor and pharmacist give you about Iscover.

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

Please read this leaflet carefully before you start taking Iscover. You may wish to keep it and read again.

What ISCOVER is used for

Iscover contains the medicine clopidogrel. Clopidogrel belongs to a group of medicines known as antiplatelet medicines.

Platelets are very small blood cells which clump together during blood clotting. By preventing this clumping, antiplatelet medicines reduce the chances of blood clots forming (a process called thrombosis).

Iscover is used to reduce blood clots forming in hardened blood vessels as they can lead to events such as stroke, heart attack or death.

You have been prescribed Iscover to help reduce blood clots forming and to reduce the risk of stroke, heart attack and death because:

- You have previously suffered a heart attack, stroke or have a condition known as peripheral arterial disease (leg pain on walking or at rest).
- You have suffered acute coronary syndrome (either a severe type of chest pain called unstable angina, or a heart attack). In this case you may also be prescribed aspirin.

Your doctor may have prescribed this medicine for another use. If you want more information, ask your doctor.

Iscover is only available on a doctor's prescription.

Before you take ISCOVER

When you must not take it:

You should not take Iscover if:

- you are allergic to clopidogrel, or to any of the ingredients listed under 'Product Description' at the end of this leaflet
- you have a medical condition that is causing bleeding such as a stomach ulcer or you have any bleeding within your head
- you suffer from severe liver disease
- you are breast feeding or intend to breast feed. Iscover passes into breast milk and, therefore, there is the possibility that the breast fed baby may be affected.
- the packaging shows signs of tampering
- the expiry date on the pack has passed. If you use this product after the expiry date has passed, it may not work.

Do not take Iscover to treat any other complaint unless your doctor says it is safe. Do not give this medicine to anyone else.

Iscover is not recommended for children because the safety and effectiveness of Iscover in children have not been established.

Before you start to take ISCOVER

You must tell your doctor if:

- you are pregnant or intend to become pregnant
Your doctor will discuss the possible risks and benefits of taking Iscover during pregnancy.
- you are planning to have an operation (including dental surgery) in the next two weeks
Your doctor will decide whether or not you need to stop Iscover prior to surgery.
- if you have or have had any medical conditions, especially the following:
 - bleeding disorders or blood clotting problems
 - liver or kidney problems
 - any illness or disability that was caused by bleeding for example impaired sight or vision because of bleeding within the eye.
 - recent serious injury.
 - recent surgery (including dental surgery).
 - allergic to other antiplatelet medicines (such as ticlopidine, prasugrel).
 - Rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption

If you have not told your doctor about any of the above, tell him/her before you start taking Iscover.

Some patients may not convert Iscover to its active form as well as other patients. These patients may not get the same benefit from Iscover.

Your doctor may advise you to go for tests to determine if Iscover will adequately work for you. Based on the test results, your doctor may change your dose of Iscover or consider alternative treatments for you.

Taking other medicines

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

Some medicines and Iscover may interfere with each other. These include:

- medicines that "thin the blood". The most common examples of these include aspirin, heparins and warfarin. There are other medicines used to 'thin the blood'. **Check with your doctor or pharmacist to see if any medicine you take may have this effect.**
- non-steroidal anti-inflammatory drugs (NSAIDs) - medicines used to treat arthritis, period pain, aches and pains,
- medicines used to treat stomach ulcers or reflux disease (also called heartburn); such as omeprazole
- some medicines used to treat infections (eg ciprofloxacin, chloramphenicol, fluconazole and voriconazole)
- some antidepressant medicines

- medicines used to treat epilepsy (e.g. carbamazepine, oxcarbazepine and phenytoin)
- medicines used to treat diabetes (eg. tolbutamide, repaglinide)
- fluvastatin - a medicine used to lower cholesterol,
- medicines used to treat breast cancer (e.g. tamoxifen, paclitaxel).
- medicines used to prevent gastric reflux - proton pump inhibitors (e.g. omeprazole)

These medicines may be affected by Iscover or affect how well Iscover works.

Your doctor may need to change the amount of your medicines, or you may need to take different medicines.

If you are unsure about any medicine you are taking you should check with your doctor or pharmacist. They will have more information on medicines to be careful with or avoid while taking Iscover.

How to take ISCOVER

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

They may differ from the information contained in this leaflet.

How much to take

The usual dose of Iscover is one 75 mg tablet daily.

If you are prescribed Iscover for the treatment of acute coronary syndrome, you may receive a starting dose of 300 mg (either one 300 mg tablet or four 75mg tablets), then one 75mg tablet daily, thereafter.

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

How to take it

Swallow the Iscover tablet with a glass of water.

When to take it

You can take Iscover before or after meals.

Take Iscover at about the same time each day. Taking your tablet at the same time each day will have the best effect. It will also help you to remember when to take it.

You should take Iscover for as long as your doctor continues to prescribe it.

If you forget to take ISCOVER

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

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.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Emergency Department at your nearest hospital, if you think that you or anyone else may have taken too much Iscover. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking ISCOVER

Things you must do:

Take Iscover exactly as your doctor has prescribed, and have any blood tests promptly when your doctor recommends that tests be done.

Tell your doctor

- if you become pregnant while taking Iscover.
- if you decide to breast feed your baby. Your doctor may want to discuss your decision and change your medicine.
- that you are taking Iscover if you are about to start on any new medicine.
- **and dentists, nurses or pharmacists that you are taking Iscover.**
Iscover may increase the risk of bleeding during an operation or some dental work. Therefore, treatment may need to be stopped before surgery. Your doctor will decide whether to stop Iscover and if so, how long before surgery.
- **immediately if you are injured while taking Iscover.**
It may take longer than usual to stop bleeding while you are taking Iscover.
- **immediately if you notice any of the following:**
abnormal bruising or bleeding; abnormal nose bleeds; red or purple blotches on your skin; bloody or black bowel motions; swelling of the face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing. (see also Side Effects section).

Things you must not do:

There are activities you should avoid while taking Iscover, for example certain sports. Sometimes after an injury bleeding may occur inside your body without you knowing about it.

Ask your doctor for advice.

Do not take Iscover to treat any other complaint unless your doctor says it is safe. Do not give this medicine to anyone else.

Do not suddenly stop taking Iscover without telling your doctor.

Things to be careful of:

Be careful driving or operating machinery until you know how Iscover affects you. As with other medicines Iscover may cause faintness or dizziness in some people. Make sure you know how you react to Iscover before you drive a car operate machinery, or do anything else that could be dangerous if you are faint or dizzy. If this occurs do not drive. If you drink alcohol faintness or dizziness may be worse.

Side Effects

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

Like other medicines Iscover can cause some side effects. Most are likely to be minor and temporary. However, some may be serious and need medical attention.

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:

- diarrhoea
- itching

- pain or stiffness in the joints
- things taste different

Tell your doctor immediately if you notice any of the following:

(NOTE: If you take both Iscover and aspirin the risk of side effects related to bleeding may be increased)

- bloody or black bowel motions
- diarrhoea with blood and mucus, stomach pain and fever
- chest pain
- abdominal or stomach pain
- nausea, vomiting, weight loss
- vomiting of blood or vomit that looks like coffee grounds
- coughing of blood
- blood in the urine
- bleeding in eyes
- unusually heavy bleeding or oozing from cuts or wounds
- unusually heavy or unexpected menstrual bleeding
- breast enlargement in men
- bleeding (including nose bleeds) or bruising more easily than normal
- rash or hives
- itching, inflamed, cracking or red skin
- red or purple spots visible through your skin
- anaemia (being tired and looking pale)
- numbness (paralysis) or problems with co-ordination
- fever, muscle weakness, loss of appetite and fatigue
- muscle pain
- faintness, dizziness, lightheadedness or blurred vision
- confusion or hallucinations
- slurred speech or other difficulty in speaking
- tightness of the chest, wheezing, coughing or difficulty breathing
- headache (severe and continuing)
- fever or other signs of infection, such as a sore throat
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- chills, sweating or clammy skin
- yellowing of the skin or whites of the eyes, vomiting, pale stools, dark urine and stomach pain with swelling

These could be more serious side effects - you may need urgent medical attention.

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 side effects. Most people do not experience any of them.

After using ISCOVER

Storage

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

If you take your tablets out of the box or blister pack they will not keep well.

Keep Iscover in a cool, dry place where the temperature stays below 25°C.

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

Do not store Iscover or any other medication in the bathroom or near a sink.

Keep Iscover 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

If your doctor tells you to stop taking Iscover, ask your pharmacist what to do with any medicine that is left over.

Product Description:

What it looks like

Iscover 75 mg tablets are pink, round tablets with 75 engraved on one side and 1171 on the other side. A box contains 28 tablets (AUST R 79021)

Active Ingredient: clopidogrel (75 mg)

Other Ingredients: mannitol, macrogol 6000, microcrystalline cellulose, hydrogenated castor oil, hypromellose, lactose, titanium dioxide, glycerol triacetate, red iron oxide and carnauba wax.

(Note: Iscover does not contain any salicylates)

Sponsored by

sanofi-aventis australia Pty Ltd
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