

Indopril Combi 4/1.25 mg Tablets

perindopril erbumine and indapamide hemihydrate.

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Indopril Combi 4/1.25 mg tablets. It does not contain all the available information about this medicine. Reading this leaflet 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 taking Indopril Combi 4/1.25 mg tablets against the expected benefits for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What INDOPRIL COMBI 4/1.25 mg tablets are

Indopril Combi 4/1.25 mg tablets. The medicine contains the active ingredients perindopril erbumine and indapamide hemihydrate.

Perindopril belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors. Indapamide belongs to a group of medicines called chlorosulphamoyl diuretics.

What INDOPRIL COMBI 4/1.25 mg tablets are used for

Indopril Combi 4/1.25 mg tablets are available only with a doctor's prescription.

There is no evidence that Indopril Combi 4/1.25 mg tablets are addictive.

Why Indopril Combi 4/1.25 mg tablets 4/1.25 mg is used for high blood pressure

Everyone has blood pressure. This pressure helps to circulate blood all around the body. Your blood pressure may be different at different times of the day, depending on how busy or stressed you are.

You have high blood pressure (also known as hypertension) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

If high blood pressure is not treated it can lead to serious health problems. You may feel fine and have no symptoms, but eventually it can cause stroke, heart disease and kidney failure.

Indopril Combi 4/1.25 mg tablets help to lower your blood pressure.

Ask your doctor if you have any questions about why Indopril Combi 4/1.25 mg tablets has been prescribed for you.

Before You Take INDOPRIL COMBI 4/1.25 mg Tablets

Do not take Indopril Combi 4/1.25 mg tablets:

There are some people who should not take Indopril Combi 4/1.25 mg tablets. Please read the lists below. If you think any of these situations apply to you, or you have any questions, please consult your doctor or pharmacist.

Do not take Indopril Combi 4/1.25 mg tablets if:

- You are allergic to perindopril, indapamide, or any of the other ingredients of Indopril Combi 4/1.25 mg tablets listed at the end of this leaflet.

- You are allergic to sulphonamide (sulpha) antibiotics, or to thiazide diuretics (a type of fluid" or "water" tablet)
- You are pregnant or trying to become pregnant.
- You are breastfeeding or plan to breast-feed.
- You undergo renal dialysis using polyacrylonitrile membranes
- You have renal artery stenosis (a problem with the blood vessels to one or both kidneys).
- You have experienced serious swelling of the face, tongue, lips or throat either suddenly or in response to another medicine in the past (a rare allergic condition known as angio-oedema).
- The packaging is torn or shows signs of tampering, or the tablets do not look quite right.
- The expiry date (EXP) on the pack has passed.

Tell your doctor if:

- You become pregnant while you are taking Indopril Combi 4/1.25 mg tablets.
- You are undergoing desensitisation treatment, or have had an allergic reaction during previous desensitisation treatment (e.g. treatments using bee, wasp or ant venom)
- You are undergoing, or have had an allergic reaction during previous, low-density lipoprotein (LDL) apheresis, a technique where LDL is 'filtered' out of a patient's blood, using dextran sulphate
- You have any other health problems, including:
 - Kidney disease.
 - Liver disease
 - High or low levels of potassium, sodium, or other problems with salt balance
 - Diabetes.
 - Gout.
 - Heart disease
 - Systemic lupus erythematosus (a disease affecting the skin, joints and kidneys).

Taking other medicines

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

Taking Indopril Combi 4/1.25 mg tablets may change the effect of some medicines, and some medicines may affect how well Indopril Combi 4/1.25 mg tablets work. You may need different amounts of your medication or to take different medicines. The medicines that may interact with Indopril Combi 4/1.25 mg tablets include the following:

- Some anaesthetic drugs
- Some drugs used to treat gout (allopurinol)
- Some steroid medicines.
- Some drugs used to treat cancer or to suppress the immune system.
- Diuretics (sometimes called "fluid" or "water" tablets)
- Lithium medications (used to treat mood swings and some types of depression)
- Sources of potassium, like potassium tablet and salt substitutes containing potassium

- Some medications used to treat high blood pressure, a fast or irregular heartbeat, and other heart conditions
- Medicines used to treat diabetes (tablets and insulin).

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Indopril Combi 4/1.25 mg tablets.

For older people or children

- Elderly people can generally use Indopril Combi 4/1.25 mg tablets safely. However, some older people have reduced kidney function - in which case additional care may be required
- Indopril Combi 4/1.25 mg tablet is not recommended for use in children.

How to take INDOPRIL COMBI 4/1.25 mg tablets

Follow all directions given to you by your doctor and pharmacist carefully. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Your doctor will select a dose when they prescribe Indopril Combi 4/1.25 mg tablets for you. The usual dose is one tablet once daily.

Swallow your tablet(s) with a glass of water, preferably in the morning.

How long to take Indopril Combi 4/1.25 mg tablets for

Indopril Combi 4/1.25 mg tablets can help to control your blood pressure, but cannot cure this condition. Indopril Combi 4/1.25 mg tablets treatment is usually for life - so you should keep taking the tablets regularly unless advised otherwise by your doctor.

If you forget to take Indopril Combi 4/1.25 mg tablets

- If your next usual dose is less than 6 hours away, just leave out the dose that you missed. Take the next dose at the usual time and continue as normal.
- If your next dose is more than 6 hours away, take the dose you have missed as soon as you realise. Then take the next dose at the usual time and continue as normal.

Do not try to make up for missed doses by taking more than one dose at a time.

If you take too much Indopril Combi 4/1.25 mg tablets

Taking too much Indopril Combi 4/1.25 mg tablets (an overdose) may cause low blood pressure (also known as hypotension). Other effects like sickness, cramps, sleepiness, confusion, kidney problems, salt and water disturbances are possible. You may require urgent medical attention.

If you think that you or anyone else may have taken too much Indopril Combi 4/1.25 mg tablets then act immediately:

- Telephone your doctor or the Poisons Information Centre (13 11 26 in Australia; 0800 764 766 in New Zealand), or go to the Accident and Emergency department at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While you are taking INDOPRIL COMBI 4/1.25 mg tablets

Things you must do

Take Indopril Combi 4/1.25 mg tablets exactly as your doctor has prescribed. Otherwise you may not get the benefits from treatment.

Tell all doctors, dentists and pharmacists who are involved with your treatment that you are taking Indopril Combi 4/1.25 mg tablets.

Make sure you drink enough water during exercise and hot weather especially if you sweat a lot. This will help you avoid any dizziness or light-headedness caused by a sudden drop in blood pressure.

Tell your doctor straight away if you have excessive vomiting or diarrhoea while taking Indopril Combi 4/1.25 mg tablets.

Things you must not do

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

Do not use Indopril Combi 4/1.25 mg tablets to treat any other complaints unless your doctor tells you to.

Do not stop taking Indopril Combi 4/1.25 mg tablets or change the dose, without checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how Indopril Combi 4/1.25 mg tablets affects you.

You may feel light-headed or dizzy when you begin to take Indopril Combi 4/1.25 mg tablets. This is because your blood pressure is falling. If you have these symptoms when standing up or getting out of bed then getting up more slowly can help. This allows your body to get used to the change in position

If you have these symptoms and they don't get better in a short time then talk to your doctor.

Side Effects

If you do not feel well while you are taking Indopril Combi 4/1.25 mg tablets then tell your doctor or pharmacist as soon as possible.

All medicines can have side effects. Most of the time they are not serious but sometimes they can be.

Indopril Combi 4/1.25 mg tablets help most people with high blood pressure, but it may sometimes have unwanted side effects. These can include:

- A dry cough
- Headache
- Feeling tired or as if you have less energy.
- Feeling faint, light-headed, or dizzy
- Feeling sick or having stomach pain
- Muscle pain.
- An increased risk of becoming dehydrated (in elderly patients and in patients with heart failure).
- Low potassium levels. Symptoms of low potassium can include a number of those listed above, and very occasionally this may be severe.

Most of these side effects are mild when they occur. Do not be alarmed by this list of possible side effects. You may not experience any of them. However, if you do - or if you notice anything else that is making you feel unwell - you should consult your doctor or pharmacist.

If any of the signs below occur then tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital:

- Swelling of your lips, face, mouth, tongue or throat
- Purple spots with occasional blisters on the front of your arms and legs and/or around your neck and ears (A rare condition known as Stevens-Johnson Syndrome)
- A fast and irregular heart beat.
- Severe blisters, skin rash, itching or other allergic reactions.

These side effects are extremely rare but can become serious.

After taking INDOPRIL COMBI 4/1.25 mg tablets

Storage

Keep Indopril Combi 4/1.25 mg tablets where children cannot reach them.

Keep tablets in the pack until it is time to take them. Indopril Combi 4/1.25 mg tablets not keep as well outside its blister packaging.

Heat and dampness can destroy some medicines.

Keep them in a cool, dry place where the temperature stays below 30°C.

Do not store medicines in a bathroom or near a sink.

Do not leave them in a car or on a windowsill.

Disposal

If your doctor tells you to stop taking Indopril Combi 4/1.25 mg tablets, or the tablets have passed their expiry date, return any leftover tablets to your pharmacist for disposal.

Product description

Australian Register Numbers:

Indopril Combi 4/1.25 mg tablets 4/1.25 mg . AUST R 147151

What Indopril Combi 4/1.25 mg tablets looks like

Perindopril erbumine and Indapamide hemihydrate tablets 4mg/1.25mg are white to off-white; capsule shaped uncoated tablets, plain on both sides containing Perindopril erbumine Ph Eur 4.0 mg and Indapamide Ph Eur 1.22 mg eq. to Indapamide hemihydrate 1.25mg.

Indopril Combi 4/1.25 mg tablets come in a blister strip. Each box contains 30 tablets.

Ingredients

Active ingredient

Each tablet of Indopril Combi 4/1.25 mg tablets contains 4mg of perindopril erbumine and 1.25mg of indapamide hemihydrate as active ingredients.

The inactive ingredients

in Indopril Combi 4/1.25 mg tablets include cellulose - microcrystalline, lactose, magnesium stearate, and silica dimethyl salicylate.

Distributor

INDOPRIL COMBI 4/1.25 mg TABLETS are distributed in Australia by:

Aspen Pharma Pty Ltd
34 -36 Chandos Street
St. Leonards, 2065, NSW
Australia

This document was updated in October 2011