

Advil® 12Hour Extended Release Tablet

Ibuprofen

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Advil 12Hour Extended Release Tablet (referred as Advil 12Hour). It does not contain all the available information. It does not take the place of talking to your pharmacist or doctor.

All medicines have benefits and risks. Your pharmacist or doctor will have weighed the risks of you taking Advil 12Hour against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your pharmacist or doctor

Keep this leaflet with your medicine.

You may need to read it again.

What Advil 12Hour is used for

Advil 12Hour is used for the temporary relief of persistent pain likely to last for more than 6 hours associated with:

- body pain
- back pain
- neck and shoulder pain
- muscle pain
- sprains and strains
- osteoarthritis
- arthritic, joint and rheumatic conditions
- period pain
- dental pain
- sinus pain
- cold and flu

Who should use Advil 12Hour

Advil 12Hour is recommended for adults and children 12 years of age and over.

How Advil 12Hour works

Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Ibuprofen, like all non-steroidal anti-inflammatory drugs, is an analgesic, antipyretic, and anti-inflammatory medication. There is strong evidence to support the view that the main mechanism of action of ibuprofen (like other NSAIDs) is related to decreasing

formation of prostaglandins. Prostaglandins are naturally-occurring fatty acid derivatives that are widely distributed in the tissues. They are believed to be a common factor in the production of pain, fever, and inflammation.

Ask your pharmacist or doctor if you have any questions about this medicine. Your pharmacist or doctor may have given it for another reason.

This medicine is not addictive.

It is only available from your pharmacist.

Before you take Advil 12Hour

When you must not take it

Do not take Advil 12Hour if you are allergic to:

- any medicines containing ibuprofen, aspirin or other NSAIDs.
- any of the ingredients in Advil 12Hour listed at the end of this leaflet.

Some of the signs and symptoms of an allergic reaction may include:

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

- rash, itching or hives on the skin

Do not take Advil 12Hour if you have/are:

- asthma that is sensitive to aspirin or NSAIDs
- a current or a past history of stomach bleeding or ulceration

Talk to your pharmacist or doctor about taking this medicine if you are over 65 years of age.

Taking this medicine may increase the risk of you getting stomach, heart or kidney problems.

- signs of gastrointestinal bleeding, such as vomiting blood, bleeding from the back passage (rectum), or have black or bloody stools
- heart failure
- kidney disease
- severe liver impairment
- have recently had coronary artery bypass surgery (CABG).

Do not take Advil 12Hour if you are pregnant or trying to become pregnant.

Do not take Advil 12Hour if the expiry date (EXP.) printed on the pack has passed or if the packaging shows signs of tampering or the tablets do not look quite right.

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

Before you start to take it

Tell your pharmacist or doctor if you:

- are allergic to any other medicines, foods, dyes or preservatives.
- you have asthma
- you have a stomach or duodenal ulcer
- you have liver or kidney disease
- you have cardiac impairment or high blood pressure
- if you are taking any products containing aspirin or salicylates
- you are taking other medications
- you are under the care of a doctor for any serious condition

Ask your pharmacist or doctor about taking the medicine if you are breastfeeding.

Very small amounts of ibuprofen pass into the breast milk. Your pharmacist or doctor will discuss the potential benefits and risks of taking the medicine if you are breastfeeding.

Taking other medicines

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

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

- aspirin, salicylates and other non-steroidal anti-inflammatory drugs (NSAIDs)
- warfarin or any other medicine used to prevent blood clots
- lithium, a medicine used to treat mood swings and some types of depression
- medicines used to lower blood pressure
- methotrexate, a medicine used to treat arthritis and some types of cancer
- medicines used to treat heart failure
- medicines such as prednisone, prednisolone and cortisone, which reduce the activity of your immune system. Taking together with ibuprofen may increase the risk of gastrointestinal bleeding.
- zidovudine, a medicine used to treat HIV infection
- probenecid, medicines used to treat diabetes and phenytoin

- SSRIs (selective serotonin reuptake inhibitors) taken together with ibuprofen may increase the risk of gastrointestinal bleeding

Tell a pharmacist or doctor if you are taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin.

Your pharmacist or doctor will have more information on these and other medicines to be careful with or avoid while taking this medicine.

If you have not told your pharmacist or doctor about any of the above, tell him/her before you start taking Advil 12Hour

How to take Advil 12Hour

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

They may differ from the information contained in this leaflet.

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

How to take Advil 12Hour

Adults and children 12 years and over:

Take 1 tablet every 12 hours while symptoms persist. Swallow the tablet whole with water - do not crush, chew, split or dissolve.

Do not take more than 1 tablet at a time.

Do not exceed 2 tablets in 24 hours.

Do not give this product to children under 12 years.

How long to take Advil 12Hour for:

Advil 12Hour should not be used for more than a few days at a time except on medical advice. If pain gets worse or last for more than a few days stop use and ask your pharmacist or your doctor.

If the pain usually lasts less than 6 hours or pain is expected to last less than 6 hours, Advil 12Hour should not be used. It is recommended to use regular Advil Tablets or Liquid Capsules.

Advil 12Hour is a bi-layer tablet. The first layer dissolves quickly to relieve pain fast. The second layer is sustained-release to give relief of persistent pain for up to 12 hours.

If Advil 12Hour does not relieve your symptoms, do not take extra tablets or any other products containing ibuprofen or other non-steroidal anti-inflammatory drugs (NSAIDs). Tell your pharmacist or your doctor.

Excessive or prolonged use can be harmful and may increase the risk of heart attack, stroke or liver damage.

If you take too much Advil 12Hour (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26, Australia or go to Accident and Emergency at the nearest hospital, if you

think you or anyone else may have taken too much Advil 12Hour. Do this even if there are no signs of discomfort or poisoning.

While you are taking Advil 12Hour

Things you must do

If you become pregnant while taking Advil 12Hour, tell your doctor immediately and stop using this product.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Advil 12Hour.

Ask your doctor or pharmacist before you start taking any new medicines.

If you are going to have surgery tell your doctor you are taking Advil 12Hour

If you are going to have any laboratory tests, tell your doctor that you are taking Advil 12Hour.

Advil 12Hour can affect the results of some of these tests.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel the tablets are not helping your condition.

Things to be careful of

Be careful driving or operating machinery until you know how Advil 12Hour affects you.

This medicine may cause dizziness in some people. If this happens, do not drive or operate heavy machinery.

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking Advil 12Hour

All medicines can have side effects.

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

Tell your doctor if you notice any of the following and they worry you. Although most people will not experience any side effects, some of the side effects that may occur with Advil 12Hour are:

- heartburn, nausea or stomach pain
- vomiting
- constipation
- abdominal pain
- bloating

- loss of appetite
- diarrhoea
- abnormal vision
- headache
- fatigue
- dizziness
- nervousness
- ringing or buzzing in the ears
- skin blisters

Side effects may be minimized by using the smallest dose for the shortest duration of time.

Tell your doctor as soon as possible if you notice any of the following:

- get sunburnt more quickly than usual

If any of the following happen, stop use and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- fluid retention
- vomiting blood, bleeding from the back passage, or bloody or black stools

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- an allergic reaction including skin reddening, rash, blisters, itching, or hives on the skin

The above list includes serious and very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare for low doses of this medicine and when used for a short period of time.

Tell your pharmacist or doctor if you notice anything that is making you feel unwell even if it is not in this list.

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

After taking Advil 12Hour

Storage

Keep Advil 12Hour 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.

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

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

Keep your tablets in a cool dry place where the temperature stays below 25C.

Do not store Advil 12Hour or any other medicine in the bathroom or near a sink.

Do not leave Advil 12Hour in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your pharmacist or doctor tells you to stop taking Advil 12Hour, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What Advil 12Hour looks like

Advil 12Hour is a white, film-coated, capsule-shaped tablet printed in blue ink on one side.

Pack sizes of 1 (professional sample), 8, 12, 14, 16, 24, 25, 28 and 32 tablets. Not all presentations may be marketed.

Ingredients

Each Advil 12Hour tablet contains ibuprofen 600 mg, 200 mg immediate release, and 400 mg extended release.

The tablet also contains the following inactive ingredients:

- carnauba wax
- colloidal anhydrous silica
- maize starch
- croscarmellose sodium
- hypromellose
- microcrystalline cellulose
- polydextrose
- macrogol 400
- pregelatinised maize starch
- sodium lauryl sulfate
- stearic acid
- titanium dioxide
- pharmaceutical ink (Opacode WB Blue NS-78-10521)

Sponsor

GlaxoSmithKline Consumer Australia Pty Limited

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Australia Toll Free Phone Number 1800 028 533

Web: www.advil.net.au

Australian registration number:

Advil 12Hour

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