

CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO Tablets

Consumer Medicine Information

Please read this information before you start taking this medicine

What is in this Leaflet?

This leaflet answers some common questions about **CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets**.

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 or pharmacist has weighed the risks of you taking **CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets** against the benefits this medicine is expected to have for you.

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

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

What are CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets used for

CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets contains two ingredients paracetamol and ibuprofen that together deliver temporary relief of acute (short term) pain and/or inflammation associated with back pain, period pain, migraine headache, sinus pain, toothache, dental procedures, cold and flu symptoms, tension headache, muscular ache, pains, headache, sore throat, tennis elbow, rheumatic pain & non-serious arthritic pain.

Paracetamol works to stop the pain messages from getting through to the brain. Paracetamol also acts in the brain to reduce fever.

Ibuprofen belongs to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). This group of medicines work by relieving pain, inflammation (swelling, redness, soreness) and fever.

Your doctor or pharmacist may have given you this medicine for another use.

CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets are not recommended for children under 12 years of age.

If you want more information, ask your doctor or pharmacist.

Before you take CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets

When you must not take it

You should not take **CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets** if you are allergic to paracetamol or ibuprofen, aspirin, other NSAIDs, or any of the ingredients listed under 'Product Description'. The symptoms of an allergic reaction may include:

- Shortness of breath
- Wheezing or difficulty breathing
- Swelling of the face or throat, lips, tongue or other parts of the body
- Rash, itching or hives on the skin
- Stomach ache, fever, chills, nausea and vomiting, fainting

If you are allergic to aspirin or NSAIDs medicines and take CHEMISTS' OWN

IBUPROFEN + PARACETAMOL DUO tablets these symptoms may be severe.

Do not take CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets if you are also taking any other medicines that contain one or more NSAID medicine, whether prescribed by your doctor or obtained without prescription.

Several medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAIDs. If you are not sure if the medicines you are taking contain these ingredients, ask your pharmacist.

Do not take this medicine if you are pregnant or plan to become pregnant. Ibuprofen should not be taken at all during the last 3 months of pregnancy including the last few days before expected birth.

Unless advised by a medical doctor, do not take Ibuprofen during the first 6 months of pregnancy.

Do not take this medicine if you have any of the following conditions:

- asthma, bronchitis, emphysema or other acute breathing difficulties
- bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea
- you have had bleeding episodes which cannot be explained
- if you have a stomach ulcer or duodenal ulcer or if you have had either of these conditions or gastric bleeding or gastrointestinal diseases in the past.
- recent vomiting of blood or material that look like coffee grounds
- you are using other paracetamol-containing products
- you are severely dehydrated after having vomited, had diarrhoea or not enough to drink
- liver or kidney disease
- heart problems

Do not take this medicine if you regularly drink large quantities of alcohol.

Ask your doctor or pharmacist about taking CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets if you are breastfeeding.

Do not use CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets in children under 12 years.

Ask your doctor or pharmacist about taking **CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets** if you are over 65 years of age and have kidney or respiratory problems.

Do not use it after the expiry date (EXP) printed on the pack.

If you take it after the expiry date it may have no effect at all, or worse, have an entirely unexpected effect.

Do not use **CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets** if the packaging is torn or shows signs of tampering.

Before you start to take it

Do not take **CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets** with other medicines containing paracetamol or ibuprofen, aspirin, salicylates or with any other anti-

inflammatory medicines, unless advised to do so by a doctor or pharmacist.

You must tell your pharmacist or doctor if:

- You have allergies to any ingredients listed under "Product Description" at the end of this leaflet.
- You have ever had any of these conditions:
 - Liver, kidney or heart problems
 - asthma, or have suffered in the past from asthma.
 - You drink large quantities of alcohol
 - You have a history of drug or alcohol abuse
 - Recent surgery on the stomach or intestines
 - Previous history of ulcers

If you currently have any of these conditions you should not take this medicine. Ask your pharmacist about taking this medicine if you are breastfeeding. Small amounts of ibuprofen and paracetamol pass into the breast milk.

Taking other medicines

Tell your pharmacist or doctor if you are using any other medicines including any of the following medicines:

- aspirin, salicylates or other NSAID medicines.
- warfarin or other medicines used to stop blood clots or thin the blood.
- Antiplatelet agents and selective serotonin reuptake inhibitors (SSRIs)
- zidovudine a medicine used to treat HIV infection.
- lithium and other medicines used to treat depression or anxiety eg MAOIs (even if taken within the last 14 days).
- Medicines to treat epilepsy or fits (seizures)
- Metoclopramide, a medicine used to control nausea and vomiting
- Propantehline, a drug used to treat stomach ulcers
- Chloramphenicol, an antibiotic used to treat ear and eye infections
- Medicines used to relieve stomach cramps or spasms
- medicines such as prednisone, prednisolone and cortisone, which reduce the activity of your immune system
- Probenecid, as drug used to treat high uric acid levels in blood associated with gout
- Cholestyramine, as drug used to reduce blood cholesterol
- Methotrexate, a medicine used to treat arthritis and some types of cancer
- Diuretics, also call fluid tablets
- Medicines used to treat high blood pressure or other heart conditions

These medicines may be affected by **CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets** or affect how well **CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets** work.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. You should also tell your pharmacist or doctor about any other medicines that you have bought without a prescription from either your pharmacy, supermarket or health food shop.

If you have not told your pharmacist or doctor about any of these things, tell him/her before you take any CHEMISTS' OWN

IBUPROFEN + PARACETAMOL DUO tablets.

How to take CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets

The label on your pack of CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets will tell you how to take your medicine and how often. If you are unsure about the directions ask your doctor or pharmacist.

How much to take

The usual dose of CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets are:

Adults and children over 12 years: 1 tablet three times a day when necessary (every 8 hours).

How long to take it

Adults: Do not take this medicine for longer than 3 days at a time unless advised to by a doctor.

Adolescents 12 – 17 years: Do not take this medicine for longer than 2 days at a time, unless advised to by a doctor.

Do not take more than 3 tablets in a 24 hour period.

Keep to the recommended dose. If CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets are not adequately controlling your pain, do not increase the dose. Please see your doctor.

Do not give this medicine to children under 12 years of age.

As with other NSAIDs, excessive or prolonged use of ibuprofen may increase the risk of heart attack, stroke or liver damage.

If your symptoms persist, worsen or new symptoms develop, talk to your doctor or pharmacist.

How to take it

Swallow tablet whole with a little water or other liquid.

The directions given to you by your pharmacist or doctor may be different from the information in this leaflet. If you are unsure what dose to take ask your pharmacist or doctor.

If you take too much (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone in Australia 13 11 26, telephone in NZ 0800764766) for advice or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention because of the risk of delayed, serious liver damage with an overdose of paracetamol.

Keep telephone numbers of these places handy.

If you take too many tablets you may feel nauseous or have upset stomach, experience vomiting and gastric irritation, feel light headed, dizzy or drowsy. Excitability, convulsions and unconsciousness may be experienced in rare cases.

While you are taking CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets

Things you must do

Take CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets exactly as your pharmacist or doctor has told you to.

Tell all your doctors, dentists and pharmacists that you are taking CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets.

Tell your doctor or pharmacist if you become pregnant while taking CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets.

Things you must NOT do

Do not use this medicine to treat any other complaint unless your doctor or pharmacist says it is safe. Do not give this medicine to anyone else even if they have the same symptoms as you.

Adults: Do not take this medicine for longer than 3 days at a time unless advised to by a doctor.

Adolescents 12 – 17 years: Do not take this medicine for longer than 2 days at a time, unless advised to by a doctor.

Do not give this medicine to children under 12 years of age.

Do not take more than the recommended dose unless your doctor tells you to.

Do not take this medicine if you are taking other medicines that contain aspirin, paracetamol, ibuprofen, salicylates or other anti-inflammatory medicines or other medicines for pain relief.

Things to be careful of

CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets may cause dizziness or drowsiness in some people, especially after the first dose. If affected do not drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or drowsy. Children should not ride bikes if affected and should be supervised to avoid potential harm.

Avoid drinking alcohol.

Drinking large quantities of alcohol while taking paracetamol may increase the risk of liver side effects.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while taking CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets.

Like other medicines, CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets can cause some side effects. If they occur, they are most likely minor and temporary. However, sometimes they are serious and need medical treatment.

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

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

- Nausea
- Stomach pain
- Loss of appetite
- Diarrhoea
- heartburn, indigestion.
- dizziness,
- light-headedness,
- drowsiness
- headache

Be careful driving or operating machinery until you know how CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets affect you.

The above list includes the more common side effects of your medicine. They are usually mild.

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

- if you got sunburnt more quickly than usual

The above list includes serious side effects that may require medical attention. Serious side effects are rare for low doses of this medicine and when used for a short period of time.

If any of the following happen, stop taking CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets and tell your pharmacist or doctor immediately or go to Accident and Emergency at your nearest hospital:

- vomiting blood
- bleeding from the back passage,
- Fluid retention
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing.
- swelling of other parts of the body
- asthma, wheezing, shortness of breath, pain or tightness in the chest
- sudden or severe itching, skin rash, hives, skin peeling

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

If you believe CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets are not working well for you, do not increase the dose. Please see your pharmacist or doctor.

Some people may get other side effects not listed above. Tell your pharmacist or doctor you notice anything else that making you feel unwell.

After taking CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets

Storage

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

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

Keep CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets in a cool dry place where the temperature stays below 25°C.

Heat and dampness can destroy some medicines.

Do not leave CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets in the car on hot days.

Do not store CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets or any other medicine in the bathroom or near a sink.

Keep CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets 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 pharmacist or doctor tells you to stop taking the tablets, ask your pharmacist what to do with any tablets that are left over.

This is not all the information that is available on CHEMISTS' OWN IBUPROFEN +

PARACETAMOL DUO tablets. If you have any more questions or are not sure about anything, ask your doctor or pharmacist.

Product Description

CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets come as white to off white, oval shaped biconvex, film-coated pearlescent tablet plain on both sides.

It is available in packs of 4, 5, 6, 8, 10, 12, 20, 24 and 30 tablets.*

* Not all pack sizes are marketed

Active ingredients:

Each tablet contains:

Paracetamol 500 mg

Ibuprofen 200 mg

Other ingredients:

starch-pregelatinised maize, povidone, crospovidone, cellulose-microcrystalline, silica-colloidal anhydrous, magnesium stearate, hypromellose, talc-purified, titanium dioxide and Opadry FX silver.

CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets do not contain any gluten, lactose, wheat or sucrose.

Name and Address of the sponsor

CHEMISTS' OWN IBUPROFEN + PARACETAMOL DUO tablets are supplied in Australia by:

Arrotex Pharmaceuticals Pty Ltd

15 – 17 Chapel Street

Cremorne VIC 3121

www.arrotex.com.au

AUST R 337244

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