

DOLAFORTE

Paracetamol and Codeine phosphate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DOLAFORTE.

It does not contain all of the available information about DOLAFORTE.

It 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 or your child taking DOLAFORTE against the benefits he/she expects it will have.

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 is DOLAFORTE FORTE

The name of your medicine is DOLAFORTE FORTE.

The active ingredients are called paracetamol and codeine phosphate.

Paracetamol belongs to a group of medicines called analgesics. Analgesics are used to block pain. It is also *antipyretic*, which means it helps reduce your

body temperature if you have a fever.

Codeine phosphate also belongs to a group of medicines called analgesics. It is an *opioid analgesic*, and it acts by blocking pain and your emotional response to pain.

DOLAFORTE is available as a tablet.

What DOLAFORTE is used for

DOLAFORTE is used to treat the following medical conditions.

- Relief of moderate to severe pain
- Fever

Your doctor, however, may have prescribed DOLAFORTE for another purpose.

Ask your doctor if you have any questions about why DOLAFORTE has been prescribed for you.

If you have any concerns, you should discuss this with your doctor.

DOLAFORTE tablets are available only with a doctor's prescription.

Before you take DOLAFORTE

When you must not take it

Do not take DOLAFORTE if you are allergic to:

- DOLAFORTE or any of its ingredients.
- Morphine
- Oxycodone

Some of the symptoms of an allergic reaction to DOLAFORTE may include red, itchy skin rashes, difficulty breathing, hay fever, swelling of the face or throat or faintness.

You should not take DOLAFORTE if you are experiencing breathing difficulties such as asthma, bronchitis or emphysema.

Do not use DOLAFORTE if you are suffering from diarrhoea caused by poisoning or antibiotics.

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

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

Do not purchase or use DOLAFORTE if the packaging is torn or shows signs of tampering.

The tablets should not be taken if they are showing visible signs of deterioration.

Do not give it to children under the age of 7 unless your doctor has prescribed it for them.

Like all medicines DOLAFORTE should not be used during pregnancy without first consulting your doctor.

DOLAFORTE is distributed into breast milk so it is not recommended for nursing mothers.

Elderly patients are more likely to have less effective kidney or liver function due to age. This may increase the risk of side effects. You should discuss how much DOLAFORTE to take with your doctor or pharmacist.

Before you start to take it

You must tell your doctor if you are:

1. allergic to any other medicines or any foods, dyes or preservatives.
2. you have any other medical conditions/ health problems, including:
 - liver disease, hepatitis
 - kidney disease or difficulty urinating
 - inflammatory bowel disease or other gastrointestinal problems

- convulsions or epilepsy
 - depression
 - Addison's disease (low activity of the adrenal gland)
 - an underactive thyroid gland
3. you are a heavy drinker or drug user.
 4. you are about to have surgery under a general anaesthetic.
 5. you have recently had gastrointestinal tract or urinary tract surgery.
 6. you have had a recent head injury or brain tumour.

If you have not told your doctor about any of the above, tell them before you take any DOLAFORTE.

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.

Do not take with other products containing paracetamol, unless your doctor says you can.

Some medicines may interfere with DOLAFORTE. These include:

- barbiturates
- medication for epilepsy

- salicylates or NSAIDs (anti-arthritis drugs)
- medicines to help you sleep, or relieve anxiety
- monoamine oxidase inhibitors (medicines for treating depression) taken within the last 10 days
- medicines to reduce blood pressure
- medicines to treat diarrhoea

The above medicines may either reduce the effectiveness of Dolaforte, reduce its own effectiveness and/ or react with Dolaforte resulting in untoward or sometimes dangerous side effects.

This list is not exhaustive. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking DOLAFORTE.

How to take DOLAFORTE

a) how much to take

Always keep to the recommended or prescribed dose.

The recommended doses of DOLAFORTE tablets are:

Adults and children over 12 years: 1 to 2 tablets every four hours as necessary.

DO NOT TAKE MORE THAN EIGHT TABLETS

IN ONE DAY.

Children 7 to 12 years:
Half a tablet every four hours as necessary.

DO NOT TAKE MORE THAN THREE TABLETS IN ONE DAY.

DOLAFORTE is not suitable for children under 7 years of age.

b) how to take it

Swallow the medicine with water. If the dose is one-half tablet, there is a break line on the tablet to help you divide it.

c) how long to take it

Adults and children over 12 years: Continue taking DOLAFORTE for no longer than a few days at a time unless the doctor advises you too.

Children 7 to 12 years
Do not take for more than 48 hours at a time unless the doctor advises you too.

If pain persists, see your doctor.

d) If you forget to take it

Take your dose as soon as you remember it, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are unsure about whether to take your next dose, speak to your doctor or pharmacist.

Do not try to make up for missed doses by taking more than one dose at a time. This may increase the chance of you getting an unwanted effect.

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 casualty at your nearest hospital, if you think that you or anyone else may have taken too much DOLAFORTE. Do this even if there are no signs of discomfort or poisoning.

Also report any other medicine or alcohol (including any barbiturates or narcotics) which has been taken. You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you take too much DOLAFORTE you may display the following symptoms: weakness, dizziness, lethargy, nausea, vomiting, sweating, mental confusion and hypotension.

While you are using DOLAFORTE FORTE

Things you must do:

Use DOLAFORTE exactly as directed or as your doctor has prescribed.

Tell your doctor if you feel DOLAFORTE is not helping your condition.

Visit your doctor regularly.

Your doctor needs to check your progress and see whether you need to keep taking DOLAFORTE

Always discuss with your doctor any problems or difficulties during or after taking DOLAFORTE .

Things you must not do:

Do not take any other medicines while you are taking DOLAFORTE without first telling your doctor.

Do not drive or operate machinery until you know how DOLAFORTE affects you.

DOLAFORTE may cause dizziness in some people and therefore may affect alertness.

Make sure you know how you react to DOLAFORTE before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or have blurred vision.

Do not give this medicine

to anyone else, even if his or her symptoms seem similar to yours.

Things to be careful of:

Be careful drinking alcohol while taking DOLAFORTE.

If you drink alcohol, it could make some of the unwanted side effects of DOLAFORTE worse.

Your doctor may suggest that you avoid alcohol completely or reduce the amount of alcohol you drink while you are taking DOLAFORTE.

Some people may experience side effects such as nausea, vomiting, constipation, drowsiness and dizziness, which may further affect the risk when driving or using dangerous machinery.

DOLAFORTE may be habit forming if used for extended periods of time.

Side effects

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

DOLAFORTE helps most people with the medical conditions listed in the beginning of this leaflet, but it may have unwanted side effects in some people, especially in elderly patients or those with underlying disorders.

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist any questions you may have.

Common Side Effects:

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

- nausea (feeling sick)
- constipation
- dizziness
- lethargy
- vomiting
- skin rashes

Some side effects are potentially serious. Contact your doctor immediately if you notice any of the following side effects:

- Signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- Breathing difficulties
- Bleeding or bruising more easily than normal
- Difficulty in urinating (passing water)
- Itchy, raised or red skin rash

Some people may get other side effects of

DOLAFORTE.

Check with your doctor as soon as possible if you have any problems while taking DOLAFORTE even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

After using DOLAFORTE

Storage

Keep it 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 DOLAFORTE in a cool dry place where the temperature stays below 30°C and protect from light.

Do not store it, or any other medicines, in a bathroom or near a sink.

Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines.

Do not take DOLAFORTE if the tablets do not look quite right.

Keep your tablets in the packaging they were provided in until it is time to take them.

Disposal

If your doctor tells you to stop taking the tablets OR they have passed their expiry date, ask your

pharmacist what to do with any left over.

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Product description

a) What it looks like

DOLAFORTE is a white capsule-shaped tablet embossed P500 C30 on one face with a single break bar on the other side. They are presented in blister packs of 20.

b) Ingredients

DOLAFORTE tablets contain paracetamol 500 mg and codeine phosphate 30 mg.

In addition each tablet contains the following inactive ingredients:

Wheat starch (gluten), microcrystalline cellulose, purified talc, magnesium stearate and gelatin.

The tablets do not contain a colouring agent.

Sponsor or Supplier

Chemists' Own Pty Ltd
(a member of Sigma group of Companies)
96 Merrindale Drive
Croydon Victoria 3136
Australia

Telephone: 03 - 9839 2800

The Australian Registration Number for DOLAFORTE tablets is AUST R 94737.

This leaflet was prepared