

Dolased Forte™

Paracetamol, codeine phosphate, doxylamine succinate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Dolased Forte™. 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 Dolased Forte™ against the benefits they expect it will have 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 Dolased Forte™ is used for

Dolased Forte™ has pain relieving, fever reducing and calmatve effects.

Dolased Forte™ is used for the relief of severe pain that does not respond to milder pain relieving drugs. This may include toothache or pain from injury or surgery and headache pain. In addition the calmatve properties of Dolased Forte™ may be especially useful in the treatment of tension headache, migraine and period pain.

It is suitable for people who cannot take aspirin for pain relief.

Dolased Forte™ is available only with a doctor's prescription.

Dolased Forte™ is not recommended for use in children under the age of 12 years.

Before you take Dolased Forte™

When you must not take it

Do not take Dolased Forte™ if you have an allergy to paracetamol, codeine phosphate, doxylamine succinate or any of the ingredients listed at the end of this leaflet.

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

- Acute breathing difficulties such as bronchitis, unstable asthma or emphysema
- Glucose-6-phosphate-dehydrogenase deficiency (an enzyme deficiency)
- Diarrhoea caused by antibiotics or poisoning

Do not take Dolased Forte™ if you have alcohol dependence.

Do not take Dolased Forte™ during the third trimester of pregnancy.

Do not take Dolased Forte™ during labour, especially if the baby is premature.

This medicine contains codeine, which may produce withdrawal effects in the newborn baby.

Do not take Dolased Forte™ if you are breastfeeding or planning to breastfeed.

Dolased Forte™ passes into breast milk and there is a possibility your baby may be affected.

Do not take Dolased Forte™ after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take Dolased Forte™ if the packaging is torn, shows signs of tampering, or if it doesn't look quite right.

If you are not sure whether you should start taking Dolased Forte™, contact your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- Liver problems
- Kidney problems
- Difficulty breathing, wheezing, chronic cough, asthma, or other chronic breathing conditions
- A history of drug dependence, including alcohol dependence
- Recent stomach, intestine or urinary tract surgery
- Prostate problems
- Underactive thyroid
- Head injury
- Fits or seizures

Tell your pharmacist or doctor if you are pregnant or plan to become pregnant.

Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Dolased Forte™.

Taking other medicines

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

Tell your doctor or pharmacist if you are taking any other medicines, which contain paracetamol, codeine or doxylamine.

Some medicines can interfere with Dolased Forte™ including:

- Any medicine causing sleepiness or drowsiness
- Medicines used to treat depression
- Some types of antihistamines
- Warfarin, a medicine used for blood clots
- Medicines used to treat diarrhoea, nausea or vomiting
- Propantheline, a drug used to treat stomach ulcers
- Medicines used to treat epilepsy or fits
- Other pain relief medication
- Medicines used to treat high blood pressure
- Chloramphenicol, an antibiotic used to treat ear and eye infections
- Medicines used to help you relax, sleep or relieve anxiety, such as barbiturates and sedatives
- Phenothiazines and antipsychotic agents, medicines used to treat mental disorders
- Zidovudine and rifampicin, drugs used to treat infections

Your doctor and pharmacist may have more information on medicines to be careful with or to avoid while taking Dolased Forte™.

How to take Dolased Forte™

How much to take

The usual adult dose is one or two tablets every 4 to 6 hours as needed for relief. Do not exceed 8 tablets in a 24 hour period.

Dolased Forte™ is not recommended for children under 12 years of age.

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

Their directions may differ from the information contained in this leaflet.

How to take it

Swallow the prescribed dose of Dolased Forte™ whole with a glass of water. It can be taken with or without food.

If you take too much (overdose)

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone in Australia 13 11 26; in New Zealand 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Dolased Forte™. Do this even if there are no signs of discomfort or poisoning.

While you are using Dolased Forte™

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Dolased Forte™.

Things you must not do

Do not give Dolased Forte™ to anyone else, even if they have the same condition as you.

Do not take Dolased Forte™ to treat any other complaints unless your doctor or pharmacist tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how Dolased Forte™ affects you.

Dolased Forte™ may cause drowsiness in some people. Make sure you know how you react to Dolased Forte™ before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy. If drowsiness occurs do not drive or operate machinery.

Avoid alcohol while you are taking Dolased Forte™.

Dolased Forte™ may be dangerous if you take large amounts over a long period of time.

Do not take high doses of the medicine for long periods of time unless your doctor tells you to.

This medicine contains codeine, which may be habit forming.

Side effects

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

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

- Skin rash
- Constipation
- Nausea and vomiting
- Drowsiness

- Sweating

These are the more common side effects of Dolased Forte™. They are usually mild.

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

- Shortness of breath
- Mouth ulcers, fever and sore throat
- Bleeding, bruising more easily
- Unusual or extreme mood swings
- Dizziness, light-headedness
- Flushing of the face
- Painful red areas with blisters and peeling layers of skin which may be accompanied by fever and/or chills
- Severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- Hepatitis (symptoms include loss of appetite, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine)

The above list includes serious side effects that may require medical attention. These side effects are rare.

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

- Wheezing or difficulty breathing
- Swelling of the face, lips, tongue or other parts of the body
- Rash, itching or hives on the skin

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

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After using Dolased Forte™

Storage

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 dark place where the temperature stays below 25°C.

Do not store Dolased Forte™ or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

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.

Disposal

If your doctor or pharmacist tells you to stop taking Dolased Forte™ or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What Dolased Forte™ looks like

Dolased Forte™ (Paracetamol, codeine phosphate and doxylamine succinate) is a round, white tablet with "T" on one side of a break line.

Dolased Forte™ is available in a blister pack in cartons of 2, 20 and 40 tablets.

Ingredients

Active ingredients

- Paracetamol 450mg
- Codeine phosphate 30mg
- Doxylamine succinate 5mg

Other ingredients

- Crospovidone
- Pre-gelatinized maize starch
- Lactose
- Povidone
- Glyceryl monostearate
- Stearic acid
- Magnesium stearate

Dolased Forte™ does not contain tartrazine or any other azo dyes.

Manufacturer

Dolased Forte™ is manufactured in Australia and supplied by:

Aspen Pharmacare Australia Pty Ltd
34-36 Chandos St
St Leonards NSW 2065

Australian Registration Number: AUST R 203987

TM - Trade Mark of Aspen Pharmacare

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