

Dolased

Paracetamol, Codeine Phosphate Hemihydrate and Doxylamine Succinate tablets

Consumer Medicine Information

WARNINGS

Limitations of use

Dolased should only be used when your doctor decides that other treatment options are not able to effectively manage your pain or you cannot tolerate them

Hazardous and harmful use

Dolased poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

Life threatening respiratory depression

Dolased can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing) even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting Dolased and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate

Use of other medicines while using Dolased

Using Dolased with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using Dolased

What is in this leaflet

This leaflet answers some common questions about *Dolased*. 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* against the benefits this medicine is expected to 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.

It contains the active ingredients paracetamol, doxylamine succinate and codeine phosphate hemihydrate.

Paracetamol, an analgesic with antipyretic action also reduces fever.

Doxylamine succinate is an antihistamine with pronounced sedative effects.

Codeine phosphate hemihydrate is an opioid analgesic, and in combination with paracetamol and doxylamine produces greater analgesia than any of these drugs alone and avoids the side effects associated with large doses of these components.

Dolased tablets contain no aspirin.

Your doctor or pharmacist may recommend *Dolased* for another reason. If you want more information ask your doctor or pharmacist.

Before you take Dolased

When you must not take it

Do not take *Dolased* if:
you have an allergy to:

- Paracetamol, codeine or doxylamine succinate, or any of the ingredients listed at the end of this leaflet
- you have had an allergic reaction to other opioid analgesic such as morphine or pethidine
- you have had an allergic reaction to other antihistamines

Symptoms of an allergic reaction to these medicines may include:

What is Dolased

The name of your medicine is *Dolased*.

What Dolased is used for

Dolased provides temporary relief of acute moderate pain and fever.

- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- hives, itching or skin rash
- fainting

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

- Ultra-rapid metaboliser of CYP 2D6
- Known intolerance to medicines used to treat or prevent pain
- Diarrhoea caused by antibiotics or poisoning
- Liver failure

Do not take Dolased if the packaging is torn or shows signs of tampering.

Do not take Dolased if the expiry date (EXP) printed on the pack has passed.

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

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

Do not give Dolased to a child under 12 years.

The safety and effectiveness of Dolased in children have not been established.

Do not give to children aged between 12 - 18 years in whom respiratory function might be compromised, including post tonsillectomy and/or adenoidectomy for obstructive sleep apnoea, due to an increased risk of developing serious and life-threatening adverse reactions

Dolased is distributed to the breast milk so do not take if you are breastfeeding. However, if your doctor advises you require codeine therapy while breastfeeding, then breastfeeding should be suspended and alternative arrangements should be made for feeding the infant for

any period during codeine treatment.

Before you start to take it

Tell your doctor if:

1. you have any allergies to:

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

2. you are pregnant or intend to become pregnant.

Your doctor will discuss the possible risks and benefits of using Dolased during pregnancy.

3. you are breast-feeding or plan to breast-feed.

Your doctor will discuss the possible risks and benefits of using Dolased during breastfeeding.

4. you have or have had any medical conditions, especially the following:

- kidney or liver disease
- breathing problems (eg. asthma)
- glaucoma
- bladder problems (urinary retention)
- prostate problems
- stomach ulcer or other stomach problems

5. you are a heavy drinker.

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

Taking other medicines

Do not take Dolased with other products containing paracetamol, unless advised to do so by a doctor or pharmacist.

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.

Some medicines may interfere with Dolased. These include:

- some drugs used to treat depression (eg. barbiturates, monoamine oxidase inhibitors)
- medication for epilepsy
- medications used to control fits (eg. Dilantin or Tegretol)
- medicines to help you sleep, or relieve anxiety
- opioid analgesics (eg. morphine or pethidine)
- some drugs used to thin the blood (anti-coagulants)
- alcohol
- Paracetamol excretion may be affected and plasma concentrations altered when given with probenecide.
- Colestyramine reduces the absorption of paracetamol if given within 1 hour of paracetamol.

These medicines may be affected by Dolased, or may affect how well it works.

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

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

How to take Dolased

How to take it

WARNING: Keep to the recommended dose.

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

Children and adolescent: Do not take this medicine for longer than 48 hours at a time unless advised to by a doctor.

Do not take with other medicines containing paracetamol unless advised to do so by a doctor.

How much to take

Dolased should be swallowed with a glass of water. They can be taken with or without food.

This medicine may cause constipation.

Adults and children over 12 years:
Take 1 - 2 tablets every 4 - 6 hours as necessary.

Do not exceed 8 tablets in a 24-hour period.

Do not give to children under 12 years of age.

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

How long to take it

Continue taking your medicine for as long as your doctor tells you. If you stop having this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea
- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating.

Dolased given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

If you take too much (overdose)

If you or someone else receive too much (overdose), and experience one or more of the symptoms below call triple zero (000) for an ambulance. Keep the person awake by talking to them or gently shaking them every now and then. You should follow the above steps even

if someone other than you have accidentally used Dolased that was prescribed for you. If someone takes an overdose they may experience one or more of the following symptoms:

- Slow, unusual or difficult breathing
- Drowsiness, dizziness or unconsciousness
- Slow or weak heartbeat
- Nausea or vomiting
- Convulsions or fits

If you think you or someone else may have used too much Dolased you should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning. When seeking medical attention, take this leaflet and remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

Depending on your body's individual ability to break down codeine, you may experience signs of overdose even when you take Dolased as recommended by your doctor. If overdose symptoms occur, seek immediate medical advice.

Things to be careful of:

You can become addicted to Dolased even if you take it exactly as prescribed. Dolased may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain.

As with all other opioid containing products, your body may become used to you taking Dolased. Taking it may result in physical dependence. Physical dependence means that you may experience

withdrawal symptoms if you stop taking Dolased suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance to Dolased may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

While you are taking Dolased

Things you must do

If you are about to start taking any new medicine tell your doctor and pharmacist that you are taking Dolased.

Tell all of the doctors, dentists, and pharmacists that are treating you that you are taking Dolased.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Dolased.

Things you must not do

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

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

Do not drink alcohol.

Things to be careful of

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

Dolased may cause drowsiness or light-headedness in some people and affect mental alertness. Make sure you know how you react to Dolased before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy. If you drink alcohol, dizziness or drowsiness could be worse.

Codeine may be habit forming if taken frequently and over a long

period of time. Please ask your doctor or pharmacist if you are concerned about this.

About 8% of people are poor metabolisers of codeine and Dolased may not work as well if you are one of those people.'

Side effects

Like other medicines, *Dolased* can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

The more common side effects of Dolased are:

- skin rashes,
- dry mouth,
- constipation
- sedation or drowsiness
- dizziness,
- nausea and vomiting,
- stomach pain

Tell your doctor or pharmacist if you notice any of these side effects and they worry you.

After taking Dolased

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 the tablets in a cool dry place where the temperature stays below 30 degrees Celcius.

Do not store *Dolased* or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep medicines 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* or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Dolased is a white biconvex capsule-shaped tablet. They are available in blister packs of 20 and 40 tablets.

Ingredients

Each *Dolased* tablet contains the following active ingredients:

- Paracetamol 500mg
- Codeine Phosphate Hemihydrate 10mg
- Doxylamine Succinate 5.1mg

The following inactive ingredients are found in *Dolased*:

- Crospovidone
- Stearic acid
- Magnesium stearate
- Lactose monohydrate
- Glyceryl monostearate - self-emulsifying
- Povidone.

Dolased contains lactose, but does not contain sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer

Aspen Pharma Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065
Website: www.aspencomi.com.au

The Australian Registration number for Dolased is AUST R 157880

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