

DOLASED tablets

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using DOLASED?

DOLASED contains a combination of three active ingredients: paracetamol, codeine phosphate hemihydrate and doxylamine succinate. DOLASED provides temporary relief of acute moderate pain and fever.

For more information, see Section [1. Why am I using DOLASED?](#) in the full CMI.

2. What should I know before I use DOLASED?

Do not use if you have ever had an allergic reaction to DOLASED or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use DOLASED?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DOLASED and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use DOLASED?

The standard dose of DOLASED for adults and children 12 years or over is one or two tablets every 4-6 hours as needed for pain relief.

More instructions can be found in Section [4. How do I use DOLASED?](#) in the full CMI.

5. What should I know while using DOLASED?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking DOLASED.• If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist 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 this medicine.
Things you should not do	<ul style="list-style-type: none">• Do not take more than 8 tablets in a 24-hour period.• Do not give DOLASED to anyone else, even if they have the same condition as you.• Do not take high doses of DOLASED for long periods of time unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Do not drive a car, operate machinery, or do anything else that could be dangerous while taking DOLASED.
Drinking alcohol	<ul style="list-style-type: none">• Do not drink alcohol while taking DOLASED.
Looking after your medicine	<ul style="list-style-type: none">• Store in a cool and dry place below 25°C.

For more information, see Section [5. What should I know while using DOLASED?](#) in the full CMI.

6. Are there any side effects?

Common side effects include skin rash, constipation, nausea, vomiting, dizziness, drowsiness, sweating, blurred vision. Serious side effects include difficulty breathing, hives or swelling of the face, lips, mouth or other parts of the body.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

WARNING:**Limitations of use**

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

Hazardous and harmful use

DOLASED contains codeine which may be habit forming. 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 (medicines used as sedatives or to treat anxiety, e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (medicines used for epilepsy or neuropathic pain e.g. gabapentin and pregabalin), antihistamines, cannabis or other central nervous system (CNS) depressants, including 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.

DOLASED tablets

Active ingredients: *paracetamol, codeine phosphate hemihydrate and doxylamine succinate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using DOLASED.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using DOLASED.

Where to find information in this leaflet:

- [1. Why am I using DOLASED?](#)
- [2. What should I know before I use DOLASED?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use DOLASED?](#)
- [5. What should I know while using DOLASED?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using DOLASED?

DOLASED contains a combination of three active ingredients, paracetamol, doxylamine succinate, and codeine phosphate hemihydrate.

DOLASED provides temporary relief of acute moderate pain and fever.

Paracetamol, an analgesic (pain-relieving medicine) with antipyretic action also reduces fever. Codeine phosphate hemihydrate is an opioid analgesic that helps to relieve pain. The body must convert codeine into morphine before it can provide pain relief. Paracetamol and codeine work

together to stop the pain messages from getting through to the brain. Doxylamine succinate is an antihistamine with calmative effects.

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

Your doctor may have prescribed it for another reason.

2. What should I know before I use DOLASED?

Warnings

Do not use DOLASED if:

- you are allergic 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:

- 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.
- you have or have had any of the following medical conditions:

- severe and/or acute respiratory disease
 - respiratory depression (shallow breathing) or respiratory insufficiency (difficulty breathing)
 - severe liver failure or impaired liver function
 - other problems with breathing such as, shallow breathing, difficulty breathing, or slow breathing
 - G6PD deficiency, a human enzyme deficiency.
- you are a CYP 2D6 ultra-rapid metaboliser (a fast metaboliser of codeine by the CYP 2D6 enzyme)
 - you are aged between 12-18 years of age and may have lowered respiratory function might be compromised including having had your tonsils or adenoids removed
 - you are pregnant or in labour, especially if the baby is premature
 - you are breastfeeding or planning to breastfeed
 - you have a history of drug dependence, including alcohol dependence
 - you are using antidepressant medication (monoamine Inhibitors (MAOIs), or have stopped taking antidepressant medication within the past 14 days
 - the person going to take the medicine is under 12 years.
 - the packaging is torn or shows signs of tampering.
 - the expiry date printed on the pack has passed.

Check with your doctor if you:

- have allergies to:
 - any other medicines
 - aspirin or any other non-steroidal anti-inflammatory drugs (NSAIDs)
 - any other substances, such as foods, preservatives or dyes
- have or have had any medical conditions, especially the following:
 - kidney or liver disease
 - Gilbert's syndrome
 - heart problems
 - low blood pressure
 - difficulty breathing, wheezing, chronic cough, asthma, or other chronic breathing conditions
 - intolerance to pain relieving medicine
 - you are a CYP 2D6 ultra-rapid metabolizer
 - chronic alcohol use including recent cessation of alcohol intake
 - low glutathione reserves
 - prostate problems
 - thyroid problems
 - multiple sclerosis
 - urinary, bowel or gallbladder conditions
 - have problems with the adrenal glands
 - convulsions, fits or seizures
 - pre-existing opioid dependence
 - chronic constipation
 - head injury or trauma
 - a history of drug dependence, including alcohol dependence. Caution is particularly for use in adolescents and young adults with a history of drug and/or alcohol abuse.
 - prone to angle closure glaucoma (high pressure in the eye)
 - difficulty or inability to pass urine

- metabolic acidosis, a condition that makes blood more acidic.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Do not take DOLASED during the third trimester of pregnancy.

Do not take DOLASED during labour, especially if the baby is premature.

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

Talk to you doctor if you are breastfeeding or intend to breastfeed.

Do not take DOLASED if you are breastfeeding or planning to breastfeed.

Use in children

Do not give DOLASED to a child under 12 years.

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

If you are over 65 years of age

Talk to your doctor or pharmacist about how much to take.

Elderly patients are more likely to have less effective kidney function due to age. This may increase the risk of side effects.

Addiction

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.

Dependence

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

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.

Withdrawal

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.

3. What if I am taking other medicines?

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

Do not take DOLASED with monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOIs.

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

Some medicines may interfere with DOLASED and affect how it works. These include:

- antihistamines
- medicines used to help relax, sleep or relieve anxiety, such as sedatives, hypnotics, gabapentinoids, cannabis and centrally active anti-emetics
- Tranquillisers (medicines used for anxiety or nerves)
- Benzodiazepines (medicines used as sedatives or to treat anxiety)
- medicines containing alcohol (ethanol), e.g. some cough syrups
- medicines which thin the blood (anti-coagulants)
- other opioid analgesics used to treat pain, e.g. morphine or pethidine
- antihypertensives (medicines used to help lower blood pressure)
- medications for epilepsy
- medications used to control fits, e.g. Dilantin or Tegretol
- metoclopramide or domperidone, medicines used to control nausea and vomiting
- propantheline, a medicine used to treat stomach ulcers
- chloramphenicol (antibiotic used to treat ear and eye infections)
- flucloxacillin, zidovudine or rifampicin, medicines used to treat infections
- antidepressants, e.g. barbiturates, monoamine oxidase inhibitors
- antipsychotics (medicines used to treat mental illnesses)
- chelating resin
- medicines used to treat alcohol and/or opioid dependence (e.g. naltrexone, buprenorphine or methadone)

- 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.

Medicines that may reduce the effect of DOLASED include:

- medicines that inhibit the liver enzyme, CYP 2D6 inhibitors such as fluoxetine, paroxetine, bupropion, cinacalcet, and methadone.
- medicines that increase the activity of the liver enzyme, CYP 3A4 inducers such as rifampicin.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DOLASED.

4. How do I use DOLASED?

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

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.

When to take DOLASED

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.

How to take DOLASED

Swallow DOLASED with a glass of water.

This medicine can be taken with or without food.

If you forget to use DOLASED

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Remember to wait 4 to 6 hours between doses.

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

If you take too much DOLASED

If you think that you or someone other than you have taken too many DOLASED tablets, urgent medical attention is needed.

Keep the person awake by talking to them or gently shaking them every now and then.

Large amounts of paracetamol can cause liver damage. If children take too many DOLASED tablets they can suffer from nightmares, hallucinations, fitting or have difficulty sleeping.

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.

Symptoms of overdose include:

- slow, unusual or difficult breathing
- drowsiness, dizziness or unconsciousness
- slow or weak heartbeat
- nausea or vomiting
- convulsions or fits
- confusion, memory loss
- difficulty walking
- changes in behaviour or personality.

You should immediately:

- phone triple zero (000) for an ambulance, or
- 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.

Report any other medicine or alcohol which has been taken.

5. What should I know while using DOLASED?

Things you should do

Remind your doctor including surgeons, dentist or pharmacist you visit that you are taking DOLASED.

Keep all your appointments, including those for blood tests.

Call your doctor straight away if you:

- feel you need to take the medicine for longer periods of time.
- feel you need to take more than the prescribed dose
- feel very unwell when you stop taking the medicine but feel better when you start taking the medicine again.

- plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.
- become pregnant while you are taking this medicine.
- are about to be started on any new medicine.

Things you should 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 take high doses of the medicine for long periods of time unless your doctor tells you to.

Do not stop taking DOLASED or change the dose without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DOLASED affects you.

DOLASED may cause drowsiness or light-headedness in some people and affect mental alertness.

Children should not ride bicycles if affected and should be supervised to avoid potential harm.

Drinking alcohol

Tell your doctor if you drink alcohol.

Do not drink alcohol while you are taking DOLASED.

Drinking alcohol increases the likelihood of becoming drowsy while taking DOLASED. Drinking alcohol and taking paracetamol at the same time can cause liver damage.

DOLASED may be habit forming if taken at high doses for extended periods of time.

Looking after your medicine

Keep your tablets in the pack until it is time to take them where the temperature stays below 25°C.

Store it in a cool dry place away from moisture, heat or sunlight. For example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

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

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Gastrointestinal related:</p> <ul style="list-style-type: none"> • nausea • vomiting • constipation • diarrhoea • dry mouth • indigestion • severe stomach pain that may be felt in the back. <p>Head and neurology related:</p> <ul style="list-style-type: none"> • depression • increased sensitivity to pain or increased levels of pain • headache. <p>Skin related:</p> <ul style="list-style-type: none"> • skin rashes • sweating • fever and chills. <p>General:</p> <ul style="list-style-type: none"> • drowsiness • sleep disturbances such as a sudden awakening from sleep with shortness of breath • trouble with sleeping (either not enough or too much) • snoring • ringing in the ear • blurred vision • visible slowing of physical and emotional reactions • thickened phlegm. <p>Urinary related:</p> <ul style="list-style-type: none"> • difficulty or inability to pass urine. 	<p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</p>
<ul style="list-style-type: none"> • trouble swallowing • chest discomfort such as pressure, heartburn or tightness. 	<p>Speak to your doctor if you have any of these side effects that may be associated with long-term use.</p>

Serious side effects

Serious side effects	What to do
<p>Heart related:</p> <ul style="list-style-type: none"> • irregular heartbeat. <p>Head and neurology related:</p> <ul style="list-style-type: none"> • feeling confused • unusual or extreme mood swings • headache • dizziness, light-headedness • fainting. <p>Bleeding-related:</p> <ul style="list-style-type: none"> • bleeding, bruising more easily • severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. <p>Liver related:</p> <ul style="list-style-type: none"> • hepatitis (symptoms include loss of appetite, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine). <p>General:</p> <ul style="list-style-type: none"> • flushing of the face • mouth ulcers, fever and sore throat • slow or shallow breathing • painful red areas with blisters and peeling layers of skin which may be accompanied by fever and/or chills. <p>Metabolism related:</p> <ul style="list-style-type: none"> • rapid breathing & heart rate and changes in consciousness caused by pyroglutamic acidosis (an accumulation of pyroglutamic acid due to low levels of a protein called glutathione). <p>Allergy related:</p> <ul style="list-style-type: none"> • swelling of the face, lips, mouth, or throat or other parts of the body • rash, itching or hives on the skin • difficulty breathing, or shallow breathing. 	<p>Call your doctor go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What DOLASED contains

Active ingredients (main ingredient)	<ul style="list-style-type: none">• paracetamol 500 mg/tablet• codeine phosphate hemihydrate 10 mg/tablet• doxylamine succinate 5.1 mg/tablet
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• compap L• crospovidone• self-emulsifying glyceryl monostearate• lactose monohydrate• magnesium stearate• povidone• stearic acid.
Potential allergens	<ul style="list-style-type: none">• sugars as lactose.

Do not take this medicine if you are allergic to any of these ingredients.

What DOLASED looks like

DOLASED is a white biconvex capsule-shaped tablet.
Available in blister packs of 40 tablets.

Australian Registration number: AUST R 157880.

Who distributes DOLASED

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

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