

MAXYDOL TABLETS

Paracetamol 500mg, Codeine Phosphate 10mg, Doxylamine Succinate 5.1mg tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Maxydol tablets. It does not contain all of the 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 Maxydol tablets against the benefits this medicine is expected to have for you.

Talk to your doctor or pharmacist if you have any concerns about taking this medicine.

Keep this leaflet with the medicine.

You may need to read it again.

What is Maxydol tablet

The name of your medicine is Maxydol tablets.

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

Paracetamol is an analgesic. It also helps in reducing fever. Codeine phosphate is an analgesic and doxylamine succinate is an antihistamine with calmative effects.

In combination, paracetamol, codeine phosphate and doxylamine produce greater analgesia than any of these drugs alone. Maxydol tablets contain no aspirin.

What Maxydol tablets is used for

Maxydol tablets provide effective temporary relief of moderate to severe pain and discomfort associated with:

- Headache (including tension and migraine)
- Period Pain
- Toothache
- Muscle Pain
- Backache
- Rheumatic Pain
- Neuralgia
- Pain associated with trauma or surgery
- Other pain where a combined analgesic & calmative action is required.

Your doctor or pharmacist may recommend Maxydol tablets for another reason.

Ask your pharmacist or doctor if you have any questions about this medicine.

This medicine may be addictive if taken for more than a few days at a time.

It is only available from your pharmacist.

Before you take Maxydol tablets

When you must not take it

Do not take Maxydol tablets if you have an allergy to:

- paracetamol, codeine or doxylamine, or any of the

ingredients listed at the end of this leaflet

- you have had an allergic reaction to other opioid analgesics such as morphine or pethidine
- you have had an allergic reaction to other antihistamines.
- Liver failure
- G6PD deficiency, a human enzyme deficiency

Do not take Maxydol if you are allergic to it or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to these medicines may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

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

- acute breathing difficulties such as bronchitis, unstable asthma or emphysema
- chronic constipation
- diarrhoea caused by antibiotics or poisoning

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

- glaucoma (high pressure in the eyes)
- stomach or duodenal ulcer, or other stomach problems
- prostate problems
- bladder problems

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

Do not take Maxydol during the third trimester of pregnancy.

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

The medicine may produce withdrawal effects in the newborn baby.

Do not take this medicine if you are also taking monoamine oxidase inhibitors, a type of medicine used to treat depression.

Do not take this medicine if you are breastfeeding or plan to breastfeed.

It passes into the breast milk and there is a possibility that the baby may be affected.

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

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

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

Do not take this medicine if you are CYP2D6 ultra-rapid metaboliser. 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

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 Maxydol tablets, contact your doctor or pharmacist.

Do not give Maxydol tablets to a child under 12 years.

Before you start to take it

Tell your doctor if:

- **you have any allergies to any other medicines or any other**

substances, such as foods, preservatives or dyes

- **any of the ingredients listed at the end of this leaflet**

- aspirin or any other NSAID medicine

- **you have a history of drug or alcohol dependence**

- 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

- **you are pregnant or intend to become pregnant**

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

- **you are breast-feeding or plan to breast-feed**

Your doctor will discuss the possible risks and benefits of using Maxydol tablets during breast-feeding.

- **you have or have had any medical conditions, especially the following:**

- kidney or liver disease
- heart problems
- difficulty breathing, wheezing, chronic cough, asthma or other chronic breathing conditions
- glaucoma a history of drug or alcohol dependence
- recent surgery on the stomach or intestines
- head injury or trauma
- enlarged prostate
- low blood pressure
- underactive thyroid
- epilepsy
- compromised respiratory function (due to emphysema, kyphoscoliosis or obesity)
- known analgesic intolerance
- if you know you are a CYP 2D6 ultra-rapid metaboliser
- chronic alcohol use including recent cessation of alcohol intake

- low glutathione reserves
- Gilbert's syndrome
- prostate problems
- thyroid problems
- Multiple sclerosis
- urinary, bowel or gallbladder conditions
- Addison's disease
- convulsions, fits or seizures
- pre-existing opioid dependence
- chronic constipation
- a history of drug dependence, including alcohol dependence. Caution is particularly recommended for use in adolescents and young adults with a history of drug and/or alcohol abuse.

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

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.

Do not take Maxydol tablets with any other products containing paracetamol, unless advised to do so by a doctor or pharmacist. Taking too much paracetamol may cause serious liver damage.

Some medicines may interfere with Maxydol tablets.

These include:

- warfarin, a medicine used to prevent blood clots
- metoclopramide, a medicine used to control nausea and vomiting
- medicines used to treat epilepsy or fits
- 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

- medicines used to relieve stomach cramps or spasms
- medicines used to prevent travel sickness
- medicines used to treat Parkinson's disease
- medicines used to treat high blood pressure
- medicines for diarrhoea, such as kaolin, pectin and loperamide
- monoamine oxidase inhibitors, medicines used to treat depression, if taken within the last 14 days
- quinidine, a medicine used to treat abnormal or irregular heart beat
- phenothiazines and antipsychotic agents, medicines used to treat mental disorders
- other opioids, used to treat pain or suppress coughs
- alcohol
- Chelating resin
- Buprenorphine
- Naltrexone
- CYP 2D6 inhibitors such as fluoxetine, paroxetine, bupropion, cinacalcet, methadone
- CYP 3A4 inducers such as rifampin

These medicines may be affected by Maxydol tablets, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

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

How to take Maxydol tablets

Follow all directions for use written on the medicine's label.

Do not take more than the recommended dose on the label or for a longer period of time.

If you are over 65 years of age, talk to your pharmacist or doctor about how much to take.

Elderly patients are more likely to have side effects from taking these medicines.

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.

Talk to your doctor or pharmacist if you do not understand the instructions on the box.

How to take it

Swallow Maxydol tablets with a glass of water. Maxydol tablets can be taken with or without food.

When to take it

Maxydol tablets can be taken with or without food.

If you are not sure when to take it, ask your doctor or pharmacist.

How long 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.

Adolescents and children over 12 years of age: Do not take this medicine for longer than 48 hours at a time unless advised to by a doctor.

Maxydol tablets is for minor and temporary ailments and should be used strictly as directed. Prolonged use without medical supervision could be harmful.

Codeine may be habit forming if taken frequently and over a long period of time.

If you are not sure how long to take Maxydol tablets, talk to your doctor or pharmacist.

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

If you forget to take it

Do not try to make up for missed doses by taking more than one dose at a time.

This may increase the chance of getting an unwanted side effect.

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

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

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (Australia 13 11 26), or go to casualty at your nearest hospital, if you think that you or anyone else may have taken too much Maxydol tablets.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep this telephone number handy.

You may need urgent medical attention. Large amounts of paracetamol can cause liver damage.

If children taken too much Maxydol tablets they can suffer nightmares, hallucinations, fitting or have difficulty sleeping.

While you are using Maxydol tablets

Things you must do

Talk to your pharmacist or doctor if your symptoms do not improve.

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

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

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

If you become pregnant while you are taking this medicine, tell your doctor or pharmacist that you are taking Maxydol.

Things you must not do

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

Do not take with other medicines containing paracetamol unless your doctor or pharmacist tells you to.

Adults: Do not take for more than a few days at a time unless your doctor tells you to.

Children and adolescents (12-17 years): Do not take for longer than 48 hours unless your doctor tells you to.

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

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

Do not drink alcohol.

Things to be careful of

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

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

Too much paracetamol may cause delayed, serious liver damage.

Only drink small quantities of alcohol (beer, wine or spirits) while taking paracetamol.

Drinking alcohol and taking paracetamol at the same time can cause liver damage. It is not recommended that you drink alcohol while taking Maxydol.

Be careful driving or operating machinery until you know how Maxydol tablets affect you.

Maxydol tablets may cause drowsiness or sleepiness in some people. If this happens, do not drive or use operate machinery. Make sure you know how you react to Maxydol tablets before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.

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

Be careful if you are over 65 and unwell or taking other medicines.

Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

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

Talk to your doctor or pharmacist if this medicine is not relieving your pain.

are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you.

Check with your doctor or pharmacist as soon as possible if you have any problems while taking Maxydol tablets, even if you do not think the problems are related with the medicine or are not listed in this leaflet.

Like other medicines, Maxydol tablets 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.

Do not be alarmed by this list of possible side effects.

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

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

- drowsiness or sleepiness
- dry mouth,
- constipation
- Difficulty breathing
- nausea
- vomiting
- dizziness
- stomach pain
- skin rashes
- Sweating
- Diarrhoea

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:

- 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,

Side Effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they

light coloured bowel motions,
dark coloured urine)

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, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- fainting
- hives
- yellowing of the skin and eyes (jaundice)

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 also occur in some patients. Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

After taking Maxydol tablets

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

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 25°C. Do not store

Maxydol tablets or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on the 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 Maxydol tablets 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

Maxydol tablets are white capsule-shaped tablets with a breakline on one side. They are available in blister packs of 20 and 40 tablets.

Ingredients

Each Maxydol tablet contains the following active ingredients:

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

The following inactive ingredients are found in Maxydol tablets:

- Starch maize
- Hydroxypropylcellulose
- Sodium lauryl sulphate
- Pregelatinized maize starch
- Silica - colloidal anhydrous
- Talc-purified
- Stearic acid
- Povidone
- Magnesium stearate

Maxydol tablets is free from preservatives, artificial flavours, artificial colours, yeast, gluten, wheat, lactose or sugar or sucrose.

Distributor

Arrow Pharma Pty Ltd
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3121

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