

Dymadon(R) Forte Tablets

Paracetamol 500 mg and codeine phosphate 30 mg

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you take Dymadon Forte Tablets.

This leaflet answers some common questions about Dymadon Forte Tablets. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you taking Dymadon Forte Tablets against the risks this medicine could 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 is Dymadon Forte used for?

Dymadon Forte is used to relieve moderate to severe pain.

Dymadon Forte contains paracetamol and codeine. Paracetamol and codeine work together to stop the pain messages from getting through to the brain.

Your doctor may have prescribed Dymadon Forte for another reason.

Before you take Dymadon Forte Tablets

Do not take if:

You must not take Dymadon Forte Tablets if:

- * you have ever had an allergic reaction to paracetamol or codeine; or any of the ingredients listed toward the end of this leaflet. (See "Ingredients")
- * you are breast feeding, unless under supervision of your doctor. Use of this product or any codeine-containing product may harm your baby.
- * **you have any of the following medical conditions:**
 - suffering from a lung disorder such as asthma, or any illness causing difficulty in breathing
 - irregular heartbeat (cardiac arrhythmias)
 - a recent head injury, or increased pressure in the head
 - seizures or a brain tumour
 - alcoholism
- * you are taking or have recently taken antidepressants of the type called monoamine oxidase inhibitors (MAOIs).
- * **the expiry date (EXP) printed on the pack has passed.**
- * **the packaging is torn or shows signs of tampering.**

Tell your doctor if:

You must tell your doctor if:

- * **you are allergic to foods, dyes, preservatives or any other medicines.**
- * **you have any other medical condition including:**
 - liver, kidney or lung problems
 - bowel disorders such as diverticulitis, ulcerative colitis or Crohn's disease
- * **you are taking any other medicines,**
especially medicines for anxiety, depression or epilepsy. Include medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Dymadon Forte Tablets can increase the effects of alcohol; antidepressants and tranquilisers; as well as some pain killers and cough and cold preparations. The combination may cause increased drowsiness.

Your doctor or pharmacist will have a complete list of the medicines that may cause problems when taken with Dymadon Forte Tablets.

- * **you are pregnant or trying to become pregnant, or you are breastfeeding.**

How do I take Dymadon Forte Tablets?

How much to take

Take Dymadon Forte Tablets as directed by your doctor or pharmacist.

The usual dosage for adults is 1 to 2 tablets, repeated in 4 hours if necessary. Do not take more than 8 tablets in 24 hours.

How to take it

The tablets should be swallowed with a little water.

Use in children

Dymadon Forte tablets are not recommended for use in children under 12 years.

What do I do if I take too much? (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much Dymadon Forte Tablets, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

While you are taking Dymadon Forte Tablets

Things you must do

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it was not working as it should

and change your treatment unnecessarily.

If you forget to take a dose, take it as soon as you remember and then go on as before, but remember not to take the tablets more often than recommended by your doctor.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Seek medical help immediately if Dymadon Forte Tablets are accidentally taken by a child.

Do not use Dymadon Forte Tablets to treat any other complaints unless your doctor says to.

Do not use this product or any codeine-containing products while breastfeeding unless under supervision of your doctor. Use of these products may harm your baby.

Things to be careful of

Dymadon Forte Tablets may cause drowsiness. It is recommended that you don't drive, use machinery or undertake any activities where alertness is required. It is unwise to drink alcohol while taking Dymadon Forte.

Dymadon Forte may be addictive if taken in high doses for extended periods of time. Please ask your doctor or pharmacist if you are concerned about this.

What are the side effects?

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking Dymadon Forte Tablets, even if the problem is not listed below.

Like other medicines, Dymadon Forte Tablets can cause some side effects. If they occur, they are most

likely to be minor and temporary.

However, some may be serious and need medical attention.

Common side-effects are:

- * **drowsiness**
- * **dizziness**
- * **nausea**
- * **vomiting**
- * **constipation**

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

Tell your doctor immediately if you notice any of the following:

- * **wheezing**
- * **swelling of the lips/mouth**
- * **difficulty in breathing**
- * **hayfever**
- * **lumpy rash (hives)**
- * **fainting.**

These could be a symptom of an allergic reaction.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

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

How do I store Dymadon Forte Tablets?

Keep this medicine where children cannot reach it, such as in a locked cupboard.

Keep Dymadon Forte Tablets in a cool, dry place where it stays below 30 degrees C. Protect from light.

Do not leave in a car, on a window sill or in the bathroom.

Keep Dymadon Forte Tablets in the blister pack until it is time to take them.

Return any unused or expired medicine to your pharmacist.

Product description

What Dymadon Forte Tablets look like

Your Dymadon Forte Tablets are white, capsule shaped tablets branded "F3B" on one side and "WELLCOME" on the other, in blister packs of 20 or 50 tablets.

Ingredients

Dymadon Forte Tablets contain the active ingredients paracetamol 500 mg and codeine phosphate 30 mg.

Dymadon Forte Tablets also contain maize starch, pre-gelatinised wheat starch, sodium starch glycollate, povidone, sodium metabisulfite, disodium edetate and magnesium stearate.

Manufacturer

Your Dymadon Forte Tablets are supplied by:

GlaxoSmithKline Australia Pty Ltd
1061 Mountain Highway
Boronia Victoria 3155
Australia.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

You may also be able to find general information about your disease and its treatment from patient information groups.

This leaflet was prepared on 19 November 2007.

The information provided applies only to Dymadon(R) Forte Tablets.

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