Consumer Medicine Information

PLEASE READ THE FOLLOWING INFORMATION CAREFULLY BEFORE YOU BEGIN TAKING FEXOTABS:

This leaflet provides a summary of the information available. It does not take the place of talking to your doctor or pharmacist who have more detailed information.

If you have any questions about FEXOTABS, or if you experience any problems when taking FEXOTABS, ask your doctor or pharmacist.

All medicines have benefits and risks, so please discuss these with your pharmacist or doctor to make sure that the benefits of taking FEXOTABS outweigh any possible risks.

Keep this leaflet with the medicine as you may want to read it again.

WHAT IS FEXOTABS AND WHAT IS IT USED FOR?

FEXOTABS tablets contain an active ingredient called "fexofenadine". It is one of a group of medicines called antihistamines.

FEXOTABS 60 is used to relieve the symptoms of seasonal and perennial allergic rhinitis (including hayfever). FEXOTABS 120 and 180 are used to relieve the symptoms of hayfever (seasonal allergic rhinitis) such as sneezing, itchy, watery or red eyes, and itchy, blocked or runny nose. FEXOTABS 180 is also used to relieve the symptoms of urticaria otherwise known as hives or itchy rash.

FEXOTABS works by blocking the action of histamine which causes these unwanted effects.

FEXOTABS is a non-sedating antihistamine which means it has been shown not to make you drowsy or slow down your reactions.

IS FEXOTABS SUITABLE FOR ME?

Do not take FEXOTABS, and tell your doctor or pharmacist if:

- you have had an allergic reaction to fexofenadine, terfenadine (Teldane?) or any of the other ingredients in FEXOTABS.
 These are listed at the end of this leaflet
- the expiry date on the pack has passed. It may have no effect or an unexpected effect if it is taken after this date
- the packaging is torn or shows signs of tampering

Before taking FEXOTABS:

You should inform your pharmacist/doctor if:

- you are, or might be, pregnant
- you are breast feeding
- you have any allergies to any other medicines, foods, preservatives or dyes
- you are taking other medicines

Your pharmacist/doctor will consider these points when recommending FEXOTABS.

Use in children:

There is currently not enough information available to recommend FEXOTABS for use in children under 12 years of age.

HOW DO I TAKE FEXOTABS?

Take FEXOTABS with a glass of water. FEXOTABS may be taken with or without food.

For the relief of the symptoms of seasonal and perennial allergic rhinitis (including hayfever) the usual dosage for adults and children over 12 years is one FEXOTABS 60mg tablet twice daily, when required.

For the relief of the symptoms of hayfever, the usual dosage for adults and children over 12 years of age is one FEXOTABS 120mg tablet daily when required, or one FEXOTABS 180mg tablet daily when required.

For relief of the symptoms of urticaria, the usual dosage for adults and children over 12 years of age is one FEXOTABS 180mg tablet daily when required.

Do not take more than the recommended dose and remember, this medicine is for you. Do not give it to anyone else, even if their symptoms seem to be the same as yours.

If FEXOTABS does not relieve your symptoms, do not take extra tablets. Tell your doctor or pharmacist.

What do I do in case of Overdose?

If you think that you or someone else may have taken too much FEXOTABS - (even if there are no signs of discomfort or poisoning) - contact your doctor or Poisons Information Centre, or go to the Casualty Department at your nearest hospital.

DOES FEXOTABS CAUSE SIDE EFFECTS?

Tell your doctor or pharmacist as soon as possible if you do not feel well while taking FEXOTABS, even if you do not think the problem is connected with the medicine or is not listed in this leaflet.

All medicines can cause side effects. Although most people will not experience any, some of the side effects that may occur with FEXOTABS are:

- headache
- tiredness
- nausea
- indigestion
- dizziness
- drowsiness

These same effects were seen in patients taking dummy or placebo capsules during the clinical studies.

How do I Store FEXOTABS?

Keep your tablets in a safe place out of the reach of children.

Store the tablets at room temperature below 25°C.

Disposal

Return any unwanted tablets to your pharmacist.

WHAT DOES FEXOTABS LOOK LIKE?

FEXOTABS 60mg tablets are peach coloured oval shaped tablets.

FEXOTABS 120mg and 180mg tablets are peach coloured and have a modified capsule shape.

FEXOTABS 60 is available in blister packs of 20 tablets.

FEXOTABS 120 and 180 are available in blister packs of 10 or 50 tablets.

What are the ingredients in FEXOTABS?

Each FEXOTABS 60 tablet contains 60mg of the active ingredient fexofenadine hydrochloride.

Each FEXOTABS 120 tablet contains 120mg of the active ingredient fexofenadine hydrochloride.

Each FEXOTABS 180 tablet contains 180mg of the active ingredient fexofenadine hydrochloride.

The inactive ingredients in FEXOTABS are: croscarmellose sodium, pregelatinised maize starch, microcrystalline cellulose, magnesium stearate, hypromellose, povidone, titanium dioxide, colloidal anhydrous silica, macrogol 400 and iron oxide.

FEXOTABS does not contain any gluten, lactose or preservatives.

DISTRIBUTOR

Aventis Pharma Pty Limited 27 Sirius Road LANE COVE NSW 2066

FEXOTABS 60mg tablets AUST R 98161 FEXOTABS 120mg tablets AUST R 98208 FEXOTABS 180mg tablets AUST R 98210

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WHERE TO GO FOR FURTHER INFORMATION

Remember this leaflet provides only a summary of some of the important things you need to know about FEXOTABS. Only your doctor or pharmacist are able to weigh up all the relevant facts and you should consult them about all aspects of this medicine as it relates to you.