

Stomach Ease Forte Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PHARMACY ACTION Stomach Ease Forte tablets.

It does not contain all available information.

It does not take the place of talking to your doctor or pharmacist. This Leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from your pharmacist and doctor and may contain important information about the medicine and its use of which you should be aware.

Keep this information with your tablets.

You may need to read it again later.

To find out more about PHARMACY ACTION Stomach Ease Forte

You should ask your doctor or pharmacist if you have any questions about your medicine or if you have any concerns about taking PHARMACY ACTION Stomach Ease Forte.

What is PHARMACY ACTION Stomach Ease Forte used for

PHARMACY ACTION Stomach Ease Forte is known as an anticholinergic medicine. It relieves the pain of stomach and bowel cramps by helping your digestive

system to relax. PHARMACY ACTION Stomach Ease Forte in packs of 10 tablets can be bought from a pharmacy without a doctor's prescription. PHARMACY ACTION Stomach Ease Forte tablets are intended for the treatment of temporary complaints.

Always consult your doctor or pharmacist if the pain does not improve within 48 hours or if pain worsens after treatment.

Before taking PHARMACY ACTION Stomach Ease Forte

When not to take PHARMACY ACTION Stomach Ease Forte

Do not take PHARMACY ACTION Stomach Ease Forte if you are allergic to hyoscine butylbromide or to any of the other ingredients in PHARMACY ACTION Stomach Ease Forte. These ingredients are listed in full at the end of this leaflet (See Ingredients).

If you are uncertain as to whether you have such an allergy you should raise this concern with your doctor or pharmacist. Some allergic reactions are:

- 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 PHARMACY ACTION Stomach Ease Forte if

you have, or have had, a prostate or heart condition.

Do not take PHARMACY ACTION Stomach Ease Forte if you have any conditions of galactose intolerance (for example, galactosaemia, the Lapp lactase deficiency or glucose-galactose malabsorption). This is because PHARMACY ACTION Stomach Ease Forte contains lactose as an ingredient.

Do not take PHARMACY ACTION Stomach Ease Forte if you have myasthenia gravis, glaucoma, porphyria or a condition of the bowel known as megacolon.

PHARMACY ACTION Stomach Ease Forte should not be used when there is a blockage in the stomach or bowel, or in certain conditions when there is reduced bowel activity.

These conditions are best explained by your doctor or pharmacist.

You should never take PHARMACY ACTION Stomach Ease Forte after the EXPIRY DATE on the product packaging.

You should not use PHARMACY ACTION Stomach Ease Forte if the packaging is torn or shows signs of tampering.

Before you start taking PHARMACY ACTION Stomach Ease Forte

Ask your doctor or pharmacist to discuss with you the things you ought to know before taking PHARMACY ACTION Stomach Ease Forte, particularly if you have not taken it before.

Before taking PHARMACY ACTION Stomach Ease Forte you must tell your doctor or pharmacist. If you are taking any other medicines, obtained with or without a doctor's prescription.

In particular you should tell your doctor or pharmacist if you are taking:

- metoclopramide
- quinidine
- amantadine
- medicines used to treat some mental conditions
- any medicine which contains antihistamines (commonly used to treat allergies)
- any medicine for the treatment of depression, heart disease or respiratory disease
- anticholinergic medicines such as tiotropium or ipratropium
- any other medicine for the treatment of this or another stomach or bowel condition

It is important to discuss this with your doctor or pharmacist because PHARMACY ACTION Stomach Ease Forte may not work as well in the presence of some other medicines or side effects may be increased.

Pregnancy

Special care is recommended during pregnancy, particularly in the first three months.

Ask for your doctor's advice if you are pregnant, or likely to become pregnant during your course of medication.

Breastfeeding

Special care is recommended if you are breastfeeding as no studies have been conducted in nursing women.

Ask for your doctor's advice if you are breastfeeding or likely to breastfeed during the course of your medication.

Children

PHARMACY ACTION Stomach Ease Forte tablets are not recommended for use in children under 6 years of age.

Ability to drive or operate machinery

In rare cases, PHARMACY ACTION Stomach Ease Forte may cause drowsiness. If affected, do not drive or operate machinery.

Alcohol

Do not drink alcohol while on medication with PHARMACY ACTION Stomach Ease Forte.

Alcohol may increase the chance of side effects such as drowsiness.

Taking PHARMACY ACTION Stomach Ease Forte

Recommended Dose

The recommended dose for adults and children over 6 years of age is one tablet up to four times a day as needed (leave at least 4-6 hours between doses).

Do not give to a child under 6 years of age. Safety and effectiveness in children younger than 6 years has not been established.

Tablets should be swallowed whole with a little fluid.

Ask your doctor or pharmacist for further information if they have advised you to take a different dose.

Do not take PHARMACY ACTION Stomach Ease Forte for longer than 2-3 days at a time except on the recommendation of a doctor. One pack of PHARMACY ACTION Stomach Ease Forte (10 tablets) is enough for 2 ½ days treatment at the recommended dose.

Discontinue taking the tablets if you no longer have pain. If the condition persists after two days of treatment,

seek medical advice as soon as possible.

Overdose

Seek medical advice if you have used more than the recommended or prescribed dose of PHARMACY ACTION Stomach Ease Forte and you experience signs of overdose as listed below.

Signs of overdose may include drowsiness, dry mouth, difficulty passing urine, reddening of the skin, decreased gastrointestinal tract movement, fast heart rate and sight disturbances.

Advice can be provided by a doctor, pharmacist or Poisons Information Centre (telephone 13 11 26).

Do not drive a car or operate machinery if you have taken more than the recommended or prescribe dose of PHARMACY ACTION Stomach Ease Forte.

While you are taking PHARMACY ACTION Stomach Ease Forte

As mentioned previously, do not drink alcohol.

Tell your doctor or pharmacist if you begin taking any other medicine while you are taking PHARMACY ACTION Stomach Ease Forte.

Cramps in the stomach or bowel may be temporary or may signal the presence of a more serious problem.

Always consult your doctor or pharmacist if the pain is severe or does not improve after 2 days of treatment with PHARMACY ACTION Stomach Ease Forte.

Tell your doctor immediately if your abdominal pain continues or worsens or occurs with symptoms like: fever, nausea, vomiting, changes in bowel movement, fainting, blood in faeces

Side effects

You should be aware that all medicines carry some risks and that all possible risks may not be known at this stage despite thorough testing. Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking this medicine.

Many of the side effects listed of PHARMACY ACTION Stomach Ease Forte are due to its anticholinergic properties.

If side effects occur, they are usually mild when PHARMACY ACTION Stomach Ease Forte is used at the recommended dose, and may disappear when you have stopped taking PHARMACY ACTION Stomach Ease Forte.

PHARMACY ACTION Stomach Ease Forte tablets may cause:

- dry mouth
- fast heart rate
- reduced sweating
- a skin condition called dyshidrosis
- difficulty with passing urine.

PHARMACY ACTION Stomach Ease Forte tablets may also cause:

- allergic reactions (such as skin rashes, or swelling of the face and difficulty in breathing).
- sudden life-threatening allergic reactions (anaphylaxis with episodes of shortness of breath and shock).

There are also some isolated reports of rare side effects from taking PHARMACY ACTION Stomach Ease Forte which may cause:

- Coma
- Hallucinations
- Dystonia
- Confusion
- Agitation
- Dizziness

If these occur seek medical advice or attention immediately. Otherwise, tell your doctor or pharmacist as soon as possible if

you experience any side effects during or after using PHARMACY ACTION Stomach Ease Forte.

Unexpected effects, not listed above, can occur with any medicine.

You should tell your doctor or pharmacist if you notice anything unusual during or after taking PHARMACY ACTION Stomach Ease Forte.

After taking PHARMACY ACTION Stomach Ease Forte

Storage

Leave all tablets in the pack until it is time to take a dose. The packaging protects the tablets.

PHARMACY ACTION Stomach Ease Forte should be kept in a cool dry place where the temperature stays below 30°C. For example, do not leave your tablets in a car or store them in the bathroom. Heat and dampness will damage the tablets.

Keep PHARMACY ACTION Stomach Ease Forte tablets where children cannot reach them.

Disposal

After the expiry date has passed, any unused PHARMACY ACTION Stomach Ease Forte should be returned to your pharmacist so that it can be disposed of safely.

Product Description

What the tablets look like

PHARMACY ACTION Stomach Ease Forte is the brand name of your tablets.

PHARMACY ACTION Stomach Ease Forte is available as film-coated tablets. These tablets are

round, biconvex and off white in colour. PHARMACY ACTION Stomach Ease Forte is available in blister packs of 10 tablets and is available from your pharmacy without a doctor's prescription (PHARMACY MEDICINE).

Each pack is identified by the following Australian Registration number which appears on the outer carton: AUST R 216124.

Ingredients

Each PHARMACY ACTION Stomach Ease Forte tablet contains:

- 20 mg hyoscine butylbromide

There are also a number of other ingredients which are used in the formation of the tablet core. These ingredients are:

- povidone
- silica - anhydrous
- lactose
- cellulose - microcrystalline
- magnesium stearate

The tablets are coated with the following proprietary ingredient:

- Opadry II White 85GI8490

Supplier

PHARMACY ACTION Stomach Ease Forte is supplied in Australia by:

Generic Health Pty Ltd, Level 1,
1102 Toorak Road
Camberwell, Vic, 3124

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