APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Atrovent® 20 HFA

metered dose inhaler

ipratropium bromide

Read all of this leaflet carefully before you start using ATROVENT 20 HFA.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your healthcare provider.
- ATROVENT 20 HFA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT ATROVENT 20 HFA CONTAINS

The active substance is ipratropium bromide.
Each metered dose (puff) contains 0,021 mg ipratropium bromide monohydrate, corresponding to 0,020 mg ipratropium bromide anhydrous.
The other ingredients are citric acid anhydrous, ethanol anhydrous (15 % *m/m*), nitrogen (inert gas) and purified water.
The propellant used is 1,1,1,2-tetrafluoroethane (HFA [hydrofluoroalkane] 134a).

2. WHAT ATROVENT 20 HFA IS USED FOR

To relieve reversible tightening of the muscles of your airways if you have:

- chronic bronchitis
- bronchial asthma
- emphysema.

3. BEFORE YOU USE ATROVENT 20 HFA

Do not use ATROVENT 20 HFA metered dose inhaler:

- If you are hypersensitive (allergic) to ipratropium bromide, atropine or similar medicines or any of the other ingredients of ATROVENT 20 HFA.
- Do not use in children.

Take special care with ATROVENT 20 HFA:

- If you suffer from narrow angle glaucoma (high pressure in the eye), prostate problems or difficulty passing urine (water).
- If you suffer from cystic fibrosis as you may be more prone to the gastrointestinal side effects of ATROVENT 20 HFA.

Eye problems have been reported and these might include stinging and pain in the eyes, blurred vision, halos around objects and coloured images, and/or red eyes if ATROVENT 20 HFA is accidentally sprayed into your eye. You should be especially careful not to allow the spray to enter the eyes. However, if any spray does get into your eyes, talk to your healthcare provider immediately for advice.

You should also talk to your healthcare provider immediately if any of the above eye problems occur at any other time, as you may be developing glaucoma which will need treatment straight away.

An immediate allergic reaction e.g. skin rash, urticaria (nettle rash), swelling of the tongue, lips and face, sudden difficulties in breathing or reduction in blood pressure may occur after administration of ATROVENT 20 HFA.

If you have the impression that ATROVENT 20 HFA is not working or is less effective than usual, or you feel that your breathing is getting worse or you need to use your inhaler more often than your healthcare provider has recommended, then you should talk to your healthcare provider immediately.

ATROVENT 20 HFA may also cause the opposite effect from what it is supposed to, namely it can make it harder for you to breathe. This can be life-threatening.
If after inhaling ATROVENT 20 HFA you feel more wheezy or experience any other difficulties in breathing, do not use any more doses (unless you have been instructed to) and consult a healthcare provider immediately.

Pregnancy and breastfeeding:
ATROVENT 20 HFA is not recommended for pregnant women or breastfeeding mothers as safety in pregnancy and lactation has not been established.
If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking this medicine.

Driving and using machinery:
You may experience undesirable effects such as dizziness and eye problems during treatment with ATROVENT 20 HFA. You should be very careful when driving a car or operating machinery when using ATROVENT 20 HFA, and you should avoid driving a car or operating machinery if you experience such side effects.

Using or taking other medicines with ATROVENT 20 HFA:
Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your healthcare provider if you are using other anticholinergic medicines (such as medicines for stomach cramps, Parkinson's Disease or travel sickness), as the long-term use of these medicines together with ATROVENT 20 HFA has not been studied and is not recommended.

Tell your healthcare provider if you use/have used other reliever inhalers or if you take/have taken any xanthine preparations e.g. theophylline or aminophylline together with ATROVENT 20 HFA as these medicines can intensify (strengthen) the bronchodilatory (opening up of the air passages of your lungs) effect attained with ATROVENT 20 HFA.

4. HOW TO USE ATROVENT 20 HFA

Do not share medicines prescribed for you with any other person.

Always use ATROVENT 20 HFA exactly as your healthcare provider has instructed you. You should check with your healthcare provider if you are unsure. You should use ATROVENT 20 HFA under medical supervision, and you should not exceed the recommended daily dose during short-term or long-term treatment. If your condition does not improve significantly with treatment, or if it gets worse, you must tell your healthcare provider. Contact your healthcare provider immediately if your breathing becomes worse quickly. The usual dose recommended for adults is two doses (puffs) four times daily. Since a requirement for increasing the doses suggests that additional kinds of treatment may be needed, a total dose of 12 puffs should not be exceeded per day.

To obtain the best results from your ATROVENT 20 HFA inhaler follow the instructions given below. If you are still unclear about how to use the device, ask your healthcare provider to explain.

Testing your inhaler:

Before first time use: to make sure that your inhaler is working, test it by pressing the base of the canister twice into the air (but away from your eyes!).

Correct use of your inhaler:

Before **each** use the following rules should be observed:

1. Remove protective cap from the mouthpiece.
2. Breathe out deeply.
3. Hold the metered dose inhaler as shown in Fig. 1. Place the mouthpiece into the mouth, closing the lips around the mouthpiece. The arrow and the base of the canister should be pointing upwards.



Fig. 1

4. Breathe in as deeply as possible and press the base of the canister firmly at the same time - this releases one dose. Hold your breath for a few seconds, then remove the mouthpiece from your mouth and breathe out. The same action should be repeated for a second inhalation.
5. Replace the protective cap after use.

6. After not using the inhaler for three days you must spray one dose to waste before use.

The plastic mouthpiece has been designed specifically for use with ATROVENT 20 HFA only, to ensure that you always get the right amount of medicine. Do not use the mouthpiece provided with ATROVENT 20 HFA with any other inhaled medicine.

The canister is under pressure and should not be opened by force or exposed to temperatures exceeding 50 °C.

The inhaler has been designed to deliver 200 puffs (doses) of ATROVENT 20 HFA. However, as the container is not see-through, it is not possible to tell when the canister is empty. Even when the 200 puffs have been used there may still be a small amount of fluid left over in the container. Therefore, please make sure that your inhaler is replaced after you have used 200 puffs (usually after 3 – 4 weeks of regular use) so that you can be certain that you are getting the right amount of ATROVENT 20 HFA in each puff.

The amount of treatment in your inhaler can be checked as follows:
Shaking the canister will show if there is any remaining fluid. Otherwise, remove the canister from the plastic mouthpiece and put it into a container of water. The contents of the canister can be estimated by observing its position in the water (see Fig. 2).

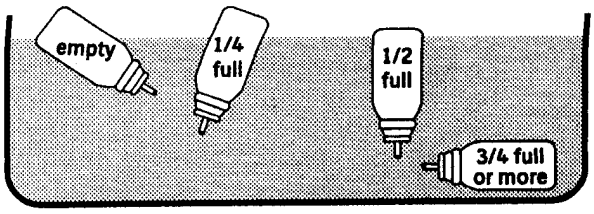
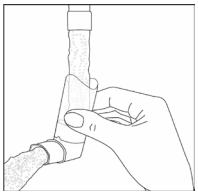


Fig. 2

Clean your inhaler at least once a week. It is important to keep the mouthpiece of your inhaler clean to ensure that residue of ATROVENT 20 HFA does not build up and block the spray.
For cleaning, first take off the dust cap and remove the canister from the inhaler. Rinse warm water through the inhaler until no medication build-up and/or dirt is visible.


Fig. 3

After cleaning, shake out the inhaler and let it air-dry without using any heating system. Once the mouthpiece is dry, replace the canister and the dust cap.

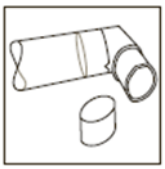


Fig. 4

Your healthcare provider will tell you how long your treatment with ATROVENT 20 HFA will last. Do not stop treatment early because it may interfere with the management of your asthma.
If you have the impression that the effect of ATROVENT 20 HFA is too strong or too weak, tell your healthcare provider.

If you use more ATROVENT 20 HFA than you should:
If you inhale too many puffs you may experience the following: dry mouth, rapid heart rate and/or blurred vision.

In the event of overdosage, consult your healthcare provider. If he/she is not available, contact the nearest hospital or poison control centre.

If you forget to use ATROVENT 20 HFA:
Inhale a dose when you remember *but* if it is near to the time for the next dose, wait until this is due. *Do not use a double dose to make up for forgotten individual doses*. Then carry on as before.

5. POSSIBLE SIDE EFFECTS

ATROVENT 20 HFA can have side effects.

The most frequent side effects reported in the clinical trials were headache, throat irritation, cough, dry mouth, movement disorders of the gut (including constipation, diarrhoea and vomiting or being sick), nausea (feeling sick) and dizziness.

If any of the following happens, stop taking ATROVENT 20 HFA and tell your healthcare provider immediately or go to the casualty department at your nearest hospital:

- If after using ATROVENT 20 HFA, you are wheezy or have other difficulties breathing, do not use any more (unless you have been told to by your healthcare provider). You may need to use a fast-acting reliever inhaler such as salbutamol, to help your breathing. Your healthcare provider may decide you need different medicines to help your breathing.
- Allergic reactions – the signs may include skin rash and itching. In severe cases there may be swelling of your mouth and face, sudden difficulties in breathing and reduction of your blood pressure, and tightening of your throat. Do not use any more ATROVENT 20 HFA.
- Palpitations (fast or uneven heart beats), increased or quickening of your heart rate, irregular heart rhythm (such as atrial fibrillation).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ATROVENT 20 HFA. You may need urgent medical attention or hospitalisation.

If any of the spray accidentally gets into your eyes, you may get eye problems such as blurred vision, enlarged pupils (the black spot in the middle of your eye), increased pressure in your eye (glaucoma), painful, stinging, redness or swelling of eyes, seeing colours or lights or halos around things, and/or difficulty focussing. If this happens, or if you get problems with your eyes at any other time, talk to your healthcare provider immediately as you may be developing glaucoma, which will need treatment straight away.

The side effects described below have been experienced by people using ATROVENT 20 HFA, and they are listed as frequent or less frequent.

Frequent:

- Headache, dizziness
- Dry mouth, feeling sick (nausea), stomach upset or discomfort
- Cough and throat irritation when you have just used ATROVENT 20 HFA.

Less frequent:

- Allergic reactions including itching, skin rash, nettle rash (urticaria). In severe cases, swelling of your mouth and face, sudden difficulties in breathing and reduction of your blood pressure, and tightening of your throat
- Wheezing or difficulties breathing, unexpected tightness of the chest, and swelling or spasm of the throat, and dry throat
- Blurred vision, enlarged pupils (the black spot in the middle of your eye), increased pressure in your eye (glaucoma), painful, stinging, redness or swelling of eyes, seeing colours or lights or halos around things, difficulty focussing
- Palpitations (fast or uneven heart beats), increased or quickening of your heart rate, irregular heart rhythm (such as atrial fibrillation)
- Frequent, loose bowel movements (diarrhoea), less frequent or difficult bowel movements (constipation), or being sick (vomiting)
- Mouth or lip sores or soreness
- Problems passing water (urine), especially if you already have problems passing water.

Not all side effects reported for ATROVENT 20 HFA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your healthcare provider for advice.
If you notice any side effects not mentioned in this leaflet, please inform your healthcare provider.

6. STORING AND DISPOSING OF ATROVENT 20 HFA

Store at or below 30 °C.

The canister contains pressurised liquid. Do not expose to temperatures exceeding 50 °C.
Do not pierce the canister or force it open.
Do not store in a bathroom.
Store all medicines out of reach of children.
Do not use after the expiry date stated on the label and carton.
Return all unused or expired medicines to your healthcare provider for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF ATROVENT 20 HFA
A metered dose inhaler consisting of a metal canister, sealed with a metering valve and fitted with a plastic mouthpiece.
Each inhaler contains 200 doses.

8. IDENTIFICATION OF ATROVENT 20 HFA
Clear, colourless liquid under pressure in a metal canister fitted with a metering valve.

9. REGISTRATION NUMBER
37/10.2.1/0273

10. NAME AND ADDRESS OF REGISTRATION HOLDER
Ingelheim Pharmaceuticals (Pty) Limited
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11. DATE OF PUBLICATION
Date of registration: 25 November 2005
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