APPROVED PATIENT INFORMATION LEAFLET

2015/06/30

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

Pulmicort® Nebulising Suspension 0,25 mg/ml (Budesonide 0,25 mg/ml) (Suspension)

Pulmicort® Nebulising Suspension 0,5 mg/ml (Budesonide 0,5 mg/ml) (Suspension)

Read all of this leaflet carefully before you start taking PULMICORT Nebulising Suspension

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- PULMICORT Nebulising Suspension 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 PULMICORT NEBULISING SUSPENSION CONTAINS:

The active substance of PULMICORT Nebulising Suspension 0,25 mg/ml & 0,5 mg/ml is budesonide.

The other ingredients are:

Citric acid anhydrous, disodium edetate, polysorbate 80, purified water, sodium chloride and sodium citrate.

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2. WHAT PULMICORT NEBULISING SUSPENSION IS USED FOR:

PULMICORT Nebulising Suspension belongs to a group of medicines called glucocorticosteroids, which are used to reduce inflammation (swelling).

Your asthma is caused by inflammation in the airways, of your lungs. PULMICORT Nebulising Suspension reduces and prevents this inflammation.

PULMICORT Nebulising Suspension should be used if your asthma is not properly controlled by the use of "relievers" (bronchodilators) or if you are unable to use an aerosol pump or inhale the medicine in a powdered form. PULMICORT Nebulising Suspension can also be used in infants and children who suffer with a severe form of croup.

PULMICORT Nebulising Suspension is to be inhaled from a nebuliser (the inhalation device). When you breathe in through the mouthpiece or a face mask, PULMICORT Nebulising Suspension will follow your breath to your lungs.

PULMICORT Nebulising Suspension will not relieve an acute attack that has already started.

3. BEFORE YOU TAKE PULMICORT NEBULISING SUSPENSION:

Do not take PULMICORT Nebulising Suspension:

- If your doctor has told you that you have chest or lung infections or if you suffer from tuberculosis (TB) or liver problems.

- If you've had any unusual reaction to budesonide (main ingredient) or to any of its other ingredients or to other medicines.

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- If your children are under 12 months.

- To provide relief if you have a severe asthma attack.

Take special care with PULMICORT Nebulising Suspension and tell your doctor, pharmacist or other health care professional:

if you are taking ketoconazole, itraconazole or cimetidine.

Facial skin irritation has occurred in some cases when a nebuliser with a face mask has been used. To prevent irritation the facial skin should be washed with water after use of the face mask.

In rare cases, more general effects of treatment with inhaled corticosteroids may occur. This may be suspected if you are feeling tired or suffer from headache, nausea or vomiting.

Pregnancy and breastfeeding:

PULMICORT Nebulising Suspension is not recommended for use during pregnancy and breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking PULMICORT.

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Driving and using machinery:

PULMICORT Nebulising Suspension has no effect on your ability to drive a car or to operate machines.

Taking other medicines with PULMICORT Nebulising Suspension:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

4. HOW TO TAKE PULMICORT NEBULISING SUSPENSION:

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

The dosage is individual. Always take PULMICORT Nebulising Suspension exactly as your doctor has instructed you. Your doctor's instructions may be different from the information contained in this leaflet. You should check with your doctor or pharmacist if you are unsure.

PULMICORT Nebulising Suspension can only be used in a nebuliser. Be sure to know how to use your nebuliser before you start taking PULMICORT Nebulising Suspension.

Before using PULMICORT Nebulising Suspension for the first time, you should read the "Instructions for use" and follow the instructions carefully.

Remember: rinse your mouth out with water after each dosing occasion. If you use a face mask, wash your face after each dosing occasion.

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Asthma:

Usual starting dose for children: 0,25-0,5 mg twice daily. If your child is using "cortisone", a higher starting dose may be given. Your doctor may after some time adjust the dose.

Usual starting dose for adults: 0,5-1 mg twice daily. Your doctor may after some time adjust the dose. After your symptoms improve, your doctor may decide to reduce the dose.

Croup:

The usual dose is 2 mg given as a single administration or as two 1 mg doses separated by 30 minutes.

If you have the impression that the effect of PULMICORT Nebulising Suspension is too strong or too weak, talk to your doctor or pharmacist.

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

Although you may already feel better during the first few days you are taking PULMICORT Nebulising Suspension, 2-4 weeks may pass before full effect is achieved. Do not forget to take PULMICORT Nebulising Suspension even when you feel well.

If you have been prescribed PULMICORT Nebulising Suspension and are still using "cortisone" tablets, your doctor may gradually (over a period of weeks or months) reduce your dose of tablets. You may even be able to eventually stop using the tablets.

Note: If your medication is changed from "cortisone" tablets to PULMICORT Nebulising

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Suspension, you may temporarily regain symptoms which may have bothered you earlier, e.g. runny nose, rash, pain in muscles and joints. If any of these symptoms bother you, or if symptoms such as headache, tiredness, nausea or vomiting occur, please contact your doctor.

Kindly refer to the "Instructions for use" at the end of this leaflet.

If you take more PULMICORT Nebulising Suspension than you should:

If you have taken more PULMICORT Nebulising Suspension than you should, you should contact your doctor immediately. If too much PULMICORT Nebulising Suspension is used on a single occasion, no harmful effects should occur. If too much is used over long period (months), it is possible that side-effects may arise. If you think that this may have happened to you, please discuss it with your doctor.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of PULMICORT Nebulising Suspension:

If you forget to take an occasional dose of PULMICORT Nebulising Suspension, it is not necessary to compensate for the dose you have missed. Just take the next dose as prescribed.

5. POSSIBLE SIDE EFFECTS:

PULMICORT Nebulising Suspension can have side effects.

Not all side effects reported for PULMICORT Nebulising Suspension are included in this leaflet. Should your general health worsen or if you experience any untoward effects while

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taking PULMICORT Nebulising Suspension, please consult your doctor, pharmacist or other health care professional for advice.

Tell your doctor if you experience one or more of the following:

Frequent side effects:

- mild irritation of the throat
- coughing
- hoarseness
- thrush (fungal infection in month and throat)

Less frequent side effects:

- skin bruising
- skin rash
- nervousness, restlessness, depression

If any of the following happens, stop taking PULMICORT Nebulising Suspension and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the face, lips, tongue and/or throat, rash, hives, itching

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice the following:

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- cramps in the airways (bronchospasm)

This is a serious side effect. You may need urgent medical attention.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF PULMICORT NEBULISING SUSPENSION:

Store at or below 30 °C. Always keep unopened single dose units in the foil envelope so they are well protected from light. Do not use PULMICORT Nebulising Suspension after the expiry date marked on the foil envelope. Record the date when the foil envelope is first opened. Do not use units from a foil envelope that has been opened for 3 months or more. Each single dose unit must be used within 12 hours after it is opened. If you do not use a full unit for each dose, protect the rest from light.

Store in an upright position. Do not freeze.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

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7. PRESENTATION OF PULMICORT NEBULISING SUSPENSION:

Each single-dose unit contains 2 ml suspension. Sheets of 5 units are packed in an envelope of foil laminate. Four foil envelopes are packed per unit carton.

8. IDENTIFICATION OF PULMICORT NEBULISING SUSPENSION:

An easily resuspendable, white to off-white suspension filled into single-dose units made of plastic. Each single dose unit has PULMICORT 0,25 mg/ml or PULMICORT 0,5 mg/ml printed on it according to its strength.

9. REGISTRATION NUMBERS:

PULMICORT Nebulising Suspension 0,25 mg/ml: 30/21.5.1/0017

PULMICORT Nebulising Suspension 0,5 mg/ml: 30/21.5.1/0016

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

AstraZeneca Pharmaceuticals (Pty) Limited

Building 2, Northdowns Office Park

17 Georgian Crescent West,

Bryanston, Johannesburg

2191, South Africa

11. DATE OF PUBLICATION:

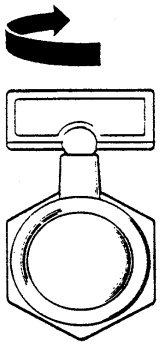
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Instructions for correct use of PULMICORT Nebulising Suspension:

Not to be used for injection. For use only in a nebuliser.

Shake the contents gently using a swirling motion.



Hold the single dose unit upright (see picture) and open by twisting off the wing.

Place the open end of the unit well into the reservoir of the nebuliser and squeeze slowly.

The single dose unit is marked with a line, which indicates the 1 ml volume when the single dose unit is held upside down. If only 1 ml is to be used, empty the contents until the surface of the liquid reaches the indicator line. Store the opened container protected from light. Before using the rest of the suspension, shake the contents carefully by using a gentle swirling motion.

The contents of an opened single dose unit should be used within 12 hours.

Single dose units in an opened envelope should be used within 3 months.

NB: Rinse the mouth out with water after inhaling the prescribed dose to minimise the risk of oropharyngeal thrush.

Wash the facial skin with water after using the face mask to prevent irritation.

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Cleaning instructions:

Adequately clean and maintain the nebuliser according to the manufacturer's instructions.

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