PACKAGE LEAFLET: INFORMATION FOR THE USER

Symbicort® Turbohaler® 200/6, inhalation powder

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. In this leaflet: What Symbicort Turbohaler is and what it is used for

Further information

swelling and inflammation in your lungs.

- Possible side effects
- 5. How to store Symbicort Turbohaler

Before you use Symbicort Turbohaler

How to use Symbicort Turbohaler

- 1. What Symbicort Turbohaler is and what it is used for
- Symbicort Turbohaler is an inhaler. It contains two different medicines: budesonide and formoterol

fumarate dihydrate.

Budesonide belongs to a group of medicines called

'corticosteroids'. It works by reducing and preventing

of medicines called 'long-acting beta, adrenoceptor agonists' or 'bronchodilators'. It works by relaxing the muscles in your airways. This helps you to breathe

Formoterol fumarate dihydrate belongs to a group

Your doctor has prescribed this medicine to treat asthma or chronic obstructive pulmonary disease (COPD). Symbicort Turbohaler can be prescribed for asthma in

more easily.

two different ways.

'reliever inhaler'.

They use Symbicort Turbohaler every day. This helps to prevent asthma symptoms from happening. They use their 'reliever inhaler' when they get asthma

symptoms, to make it easier to breathe again.

inhalers: Symbicort Turbohaler and a separate

a) Some people are prescribed two asthma

as their only asthma inhaler. They use Symbicort Turbohaler every day. This helps

b) Some people are prescribed Symbicort Turbohaler

- to prevent asthma symptoms from happening. They also use Symbicort Turbohaler when they need
- extra doses for relief of asthma symptoms, to make it easier to breathe again. They do not need a separate inhaler for this.
- Chronic obstructive pulmonary disease (COPD) Symbicort Turbohaler can also be used to treat the symptoms of severe COPD in adults. COPD is a longterm disease of the airways in the lungs, which is often

You are allergic (hypersensitive) to budesonide,

Take special care with Symbicort Turbohaler

formoterol, or the other ingredient, which is lactose (which contains small amounts of milk proteins).

Do not use Symbicort Turbohaler if:

2. Before you use Symbicort Turbohaler

caused by cigarette smoking.

You are diabetic. You have a lung infection. You have high blood pressure or you have ever had a heart problem (including an uneven heart beat, a very

fast pulse, narrowing of the arteries or heart failure).

Before you use Symbicort Turbohaler, tell your doctor or

You have problems with your thyroid or adrenal glands.

pharmacist if:

You have low levels of potassium in your blood. You have severe liver problems.

pressure.

Taking other medicines

taking any of the following medicines:

the anti-depressant nefazodone.

- Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription and
- herbal medicines. In particular, tell your doctor or pharmacist if you are

Beta-blocker medicines (such as atenolol or

eyedrops (such as timolol for glaucoma).

propranolol for high blood pressure), including

quinidine). Medicines like digoxin, often used to treat heart failure. Diuretics, also known as 'water tablets' (such as

furosemide). These are used to treat high blood

Medicines for a fast or uneven heart beat (such as

- Steroid medicines that you take by mouth (such as prednisolone). Xanthine medicines (such as theophylline or
- Other bronchodilators (such as salbutamol). Tricyclic anti-depressants (such as amitriptyline) and

aminophylline). These are often used to treat asthma.

MAOIs (such as phenelzine). Phenothiazine medicines (such as chlorpromazine and prochlorperazine).

Mono-Amine Oxidase Inhibitors, also known as

- Medicines called 'HIV-protease inhibitors' (such as ritonavir) to treat HIV infection. Medicines to treat infections (such as ketoconazole,
- clarithromycin and telithromycin). Medicines for Parkinson's disease (such as leva-dopa).

itraconazole, voriconazole, posaconazole,

Medicines for thyroid problems (such as levo-thyroxine).

If any of the above applies to you, or if you are not

- sure, talk to your doctor or pharmacist before using Symbicort Turbohaler.
- Also tell your doctor or pharmacist if you are going to have a general anaesthetic for an operation or for dental work.

If you are pregnant, or planning to get pregnant, talk to your doctor before using Symbicort Turbohaler - do

ability to drive or to use tools or machines.

Pregnancy and breast-feeding

- not use Symbicort Turbohaler unless your doctor tells you to. If you get pregnant while using Symbicort Turbohaler, do not stop using Symbicort Turbohaler but talk to
- your doctor immediately. If you are breast-feeding, talk to your doctor before using Symbicort Turbohaler.
- Driving and using machines Symbicort Turbohaler has no or negligible effect on your

budesonide, formoterol fumarate dihydrate Read all of this leaflet carefully before you start Important information about some of the taking this medicine. ingredients of Symbicort Turbohaler

Symbicort Turbohaler contains lactose, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before using this medicine. The amount of lactose in this medicine does not normally cause problems in people who are lactose intolerant. The excipient lactose contains small amounts of milk

proteins, which may cause an allergic reaction. 3. How to use Symbicort Turbohaler

Always use Symbicort Turbohaler exactly as your doctor has told you. You should check with your

- doctor or pharmacist if you are not sure. It is important to use Symbicort Turbohaler every day, even if you have no asthma or COPD symptoms at
- If you are using Symbicort Turbohaler for asthma, your doctor will want to regularly check your symptoms. If you have been taking steroid tablets for your asthma

or COPD, your doctor may reduce the number of tablets that you take, once you start to use Symbicort Turbohaler. If you have been taking oral steroid tablets for a long time, your doctor may want you to have blood tests

from time to time. When reducing oral steroid tablets,

you may feel generally unwell even though your chest

symptoms may be improving. You might experience

symptoms such as a stuffy or runny nose, weakness or joint or muscle pain and rash (eczema). If any of these symptoms bother you, or if symptoms such as headache, tiredness, nausea (feeling sick) or vomiting (being sick) occur, please contact your doctor immediately. You may need to take other medication if you develop allergic or arthritic symptoms. You should speak to your doctor if you

are concerned as to whether you should continue to use

Your doctor may consider adding steroid tablets to your

when you have a chest infection or before an operation).

usual treatment during periods of stress (for example,

Important information about your asthma or COPD If you feel you are getting breathless or wheezy while using Symbicort Turbohaler, you should continue to use Symbicort Turbohaler but go to see your doctor as soon

Your breathing is getting worse or you often wake up at night with asthma. Your chest starts to feel tight in the morning or your

as possible, as you may need additional treatment.

Contact your doctor immediately if:

chest tightness lasts longer than usual. These signs could mean that your asthma or COPD is not being properly controlled and you may need different or additional treatment immediately.

Asthma Symbicort Turbohaler can be prescribed for asthma in two different ways. The amount of Symbicort Turbohaler

to use and when to use it depends on how it has been

a) If you have been prescribed Symbicort Turbohaler and a separate reliever inhaler, read the section called 'a) Using Symbicort Turbohaler and a separate

prescribed for you.

reliever inhaler

Adults (18 years and above)

Symbicort Turbohaler.

reliever inhaler'. b) If you have been prescribed Symbicort Turbohaler as your only inhaler, read the section called 'b) Using Symbicort Turbohaler as your only asthma inhaler'. a) Using Symbicort Turbohaler and a separate

The usual dose is 1 or 2 inhalations, twice a day. Your doctor may increase this to 4 inhalations, twice a day. If your symptoms are well controlled, your doctor

Use your Symbicort Turbohaler every day. This

helps to prevent asthma symptoms from happening.

may ask you to take your medicine once a day. Adolescents (12 to 17 years)

The usual dose is 1 or 2 inhalations, twice a day. If your symptoms are well controlled, your doctor may ask you to take your medicine once a day.

for children aged from 6 to 11 years. Symbicort Turbohaler is not recommended to be used

in children who are younger than 6 years. Your doctor (or asthma nurse) will help you to manage

A lower strength of Symbicort Turbohaler is available

do not adjust the dose without talking to your doctor (or asthma nurse) first. Use your separate 'reliever inhaler' to treat asthma symptoms when they happen. Always keep your

b) Using Symbicort Turbohaler as your only asthma

'reliever inhaler' with you to use when you need it.

Do not use Symbicort Turbohaler to treat asthma

symptoms - use your reliever inhaler.

your asthma. They will adjust the dose of this medicine

to the lowest dose that controls your asthma. However,

inhaler Only use Symbicort Turbohaler in this way if your doctor has told you to and if you are aged 18 or above. Use your Symbicort Turbohaler every day. This helps to prevent asthma symptoms from happening. You can take:

1 inhalation in the morning and 1 inhalation in the

Your doctor may increase this to 2 inhalations twice a day. Also use Symbicort Turbohaler as a 'reliever inhaler' to treat asthma symptoms when they happen.

2 inhalations in the morning

2 inhalations in the evening.

evening

or

or

wait a few minutes. If you do not feel better, take another inhalation. Do not take more than 6 inhalations at a single time.

- Always keep your Symbicort Turbohaler with you, so you can use it when you need it.
- A total daily dose of more than 8 inhalations is not normally needed. However, your doctor may allow you
- to take up to 12 inhalations a day for a limited period.

If you get asthma symptoms, take 1 inhalation and

- If you regularly need to use 8 or more inhalations a
- day, make an appointment to see your doctor or nurse. They may need to change your treatment.
- Do not use more than 12 inhalations in total in 24 hours. If you are doing exercise and you get asthma symptoms,
- use Symbicort Turbohaler as described here. However, do not use Symbicort Turbohaler just before exercise to stop asthma symptoms from happening.

Only to be used by adults (aged 18 years and above). The usual dose is 2 inhalations twice a day. Your doctor may also prescribe other bronchodilator drugs, for example anticholinergics (such as tiotropium

or ipratropium bromide) for your COPD disease.

Chronic Obstructive Pulmonary Disease (COPD)

Preparing your new Symbicort Turbohaler Before using your **new** Symbicort Turbohaler **for the** first time, you need to prepare it for use as follows: Unscrew the cover and lift it off. You

may hear a rattling sound. Hold your Turbohaler upright with the red grip at the bottom. Turn the red grip as far as it will go in



Every time you need to take an inhalation, follow the

instructions below. 1. Unscrew the cover and lift it off. You may hear a rattling sound.

one direction. Then turn it as far as it

not matter which way you turn it first).

Do this again, turning the red grip in

Your Turbohaler is now ready for use.

will go in the other direction (it does

You should hear a click sound.

both directions.

How to take an inhalation

Hold your Turbohaler upright with the red grip at

the bottom. Do not hold the mouthpiece when you load your Turbohaler. To load your Turbohaler with a dose, turn

the red grip as far as it will go in one direction. Then

turn it as far as it will go in the other direction (it does not matter which way you turn it first). You should

hear a click sound. Your Turbohaler is now loaded and ready to use. Only load your Turbohaler when you need to use it. 4. Hold your Turbohaler away from your mouth.

bite on the mouthpiece.

your Turbohaler.

Cleaning your Turbohaler

dry tissue. Do not use water or liquids.

When to start using a new Turbohaler

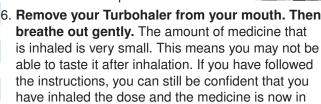
either 60 or 120 doses when it is full.

The dose indicator is marked in

The dose indicator tells you how many doses

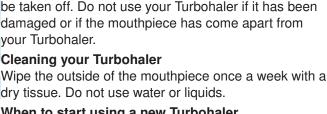
breathe out through your Turbohaler. 5. Place the mouthpiece gently between your teeth. Close your lips. Breathe in as deeply and as hard as you can through your mouth. Do not chew or

Breathe out gently (as far as is comfortable). Do not



7. If you are to take a second inhalation, repeat steps 2 to 6. 8. Replace the cover tightly after use. 9. Rinse your mouth with water after your daily morning and/or evening doses, and spit it out. Do not try to remove or twist the

mouthpiece. It is fixed to your Turbohaler and must not



intervals of 10 doses. Therefore it does not show every dose. When you first see a red mark at the edge of the indicator window, there are approximately 20 doses left. For the last

10 doses, the background of the dose indicator is

red. When the '0' on the red background has reached

the middle of the window, you must start using your

(inhalations) are left in your Turbohaler, starting with

new Turbohaler. The grip will still twist and 'click' even when your Turbohaler is empty. The sound that you hear as you shake your

much medicine is left in your Turbohaler.

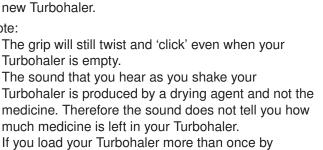
mistake before taking your dose, you will still only

receive one dose. However, the dose indicator will

It is important that you take your dose as stated on

the pharmacist's label or as advised by your doctor.

You should not exceed your prescribed dose without



register all the loaded doses. If you use more Symbicort Turbohaler than you should

seeking medical advice.

forgotten dose.

immediately:

dose, skip the missed dose.

product, ask your doctor or pharmacist.

The most common symptoms that may occur if you use more Symbicort Turbohaler than you should are trembling, headache or a rapid heart beat. If you forget to use Symbicort Turbohaler If you forget to take a dose, take it as soon as you

remember. However, if it is nearly time for your next

Do not take a double dose to make up for a

If you have any further questions on the use of this

4. Possible side effects Like all medicines, Symbicort Turbohaler can cause side effects, although not everybody gets them. If either of the following happen to you, stop using

Symbicort Turbohaler and talk to your doctor

(tongue and/or throat and/or difficulty swallowing) or hives together with difficulty breathing (angioedema) and/or sudden feeling of faintness. This may mean that you are having an allergic reaction. This happens

immediately as you may need to have your treatment changed. This happens very rarely,

affecting less than 1 in 10,000 people.

Swelling of your face, particularly around your mouth

rarely, affecting less than 1 in 1,000 people. Sudden acute wheezing or shortness of breath immediately after using your inhaler. If either of these symptoms occur, stop using your Symbicort Turbohaler straightaway and use your 'reliever' inhaler. Contact your doctor

Palpitations (awareness of your heart beating), trembling or shaking. If these effects occur, they are usually mild and usually disappear as you continue to

Common (affects less than 1 in 10 people)

Other possible side effects:

use Symbicort Turbohaler.

likely if you rinse your mouth out with water after using your Symbicort Turbohaler. Mild sore throat, coughing and a hoarse voice. Headache.

Thrush (a fungal infection) in the mouth. This is less

Uncommon (affects less than 1 in 100 people) Feeling restless, nervous or agitated. Disturbed sleep. Feeling dizzy.

Nausea (feeling sick). Fast heart beat. Bruising of the skin.

Muscle cramps. Rare (affects less than 1 in 1,000 people) Rash, itching.

Bronchospasm (tightening of the muscles in the airways which causes wheezing). If the wheezing

doctor immediately.

the mouth.

adolescents

comes on suddenly after using Symbicort Turbohaler stop using Symbicort Turbohaler and talk to your

Low levels of potassium in your blood.

Uneven heart beat. Very rare (affects less than 1 in 10,000 people) Depression. Changes in behaviour, especially in children.

An increase in the amount of sugar (glucose) in your blood. Taste changes, such as an unpleasant taste in

Chest pain or tightness in the chest (angina pectoris).

Changes in your blood pressure. Inhaled corticosteroids can affect the normal production of steroid hormones in your body,

particularly if you use high doses for a long time. The effects include:changes in bone mineral density (thinning of the bones) cataract (clouding of the lens in the eye)

a slowing of the rate of growth of children and

glaucoma (increased pressure in the eye)

the kidney). These effects are much less likely to happen with inhaled corticosteroids than with corticosteroid tablets. If any of the side effects get serious or if you notice

any side effects not listed in this leaflet, please tell your

an effect on the adrenal gland (a small gland next to

doctor or pharmacist. 5. How to store Symbicort Turbohaler Keep out of the reach and sight of children.

stated on the carton or on the label of your inhaler after

EXP. The expiry date refers to the last day of that month

Do not store above 30°C. Keep the container/cap tightly closed, in order to protect from moisture. Medicines should not be disposed of via wastewater

or household waste. Ask your pharmacist how to

dispose of medicines no longer required. These

measures will help to protect the environment.

The other ingredient is lactose monohydrate (which

your medicine. The inhalation powder is white in colour.

has a white body with a red turning grip. The turning grip

contains a Braille code with the number 6 for identification,

Each Turbohaler contains either 60 or 120 doses and

What Symbicort Turbohaler 200/6 contains

Do not use the inhaler after the expiry date that is

The active substances are budesonide and formoterol fumarate dihydrate. Each inhaled dose contains 200 micrograms of budesonide and 6 micrograms of formoterol fumarate dihydrate.

6. Further information

contains milk proteins). What Symbicort Turbohaler 200/6 looks like and contents of the pack Symbicort Turbohaler 200/6 is an inhaler containing

to differ from other AstraZeneca inhaled products. Symbicort Turbohaler 200/6 is available in packs of 1, 2, 3, 10 or 18 Turbohalers containing 60 or 120 doses.

Not all pack sizes may be marketed. Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for Symbicort Turbohaler 200/6

is held by AstraZeneca UK Ltd, 600 Capability Green,

Luton LU1 3LU, UK. Symbicort Turbohaler 200/6 is manufactured by

Symbicort Turbohaler and Symbicort Turbuhaler. In some countries, the dosage strength refers to the metered dose

AstraZeneca AB, S-151 85 Södertälje, Sweden. Symbicort Turbohaler is authorised in the Member States of the EEA under the following names:

(200/6), in others the delivered dose (160/4.5).

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the

following information:

Product name Symbicort Turbohaler 200/6

Reference number

17901/0092 This is a service provided by the

Royal National Institute of Blind People.

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