PACKAGE LEAFLET: INFORMATION FOR THE USER

Symbicort® Turbohaler® 200/6, inhalation powder

budesonide, formoterol fumarate dihydrate

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.

 This modicine has been prescribed for you. Do not
- 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

Nynat Sym Refore you

- 2. Before you use Symbicort Turbohaler
- 3. How to use Symbicort Turbohaler
- 4. Possible side effects
 5. How to store Symbicort Turbobaler
- 5. How to store Symbicort Turbohaler6. Further information
- What Symbicort Turbohaler is and what it is used for

swelling and inflammation in your lungs.

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

Formoterol fumarate dihydrate belongs to a group of medicines called 'long-acting beta₂ adrenoceptor agonists' or 'bronchodilators'. It works by relaxing the muscles in your airways. This helps you to breathe

Your doctor has prescribed this medicine to treat asthma or chronic obstructive pulmonary disease (COPD).

Asthma

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

- b) Some people are prescribed Symbicort Turbohaler as their only asthma inhaler.
 They use Symbicort Turbohaler every day. This helps
- 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 long-

term disease of the airways in the lungs, which is often

2. Before you use Symbicort Turbohaler Do not use Symbicort Turbohaler if:

 You are allergic (hypersensitive) to budesonide, formoterol, or the other ingredient, which is lactose (which contains small amounts of milk proteins).

Before you use Symbicort Turbohaler, tell your doctor or

Take special care with Symbicort Turbohaler

 You have high blood pressure or you have ever had a heart problem (including an uneven heart beat, a very

You are diabetic.

You have a lung infection.

You have severe liver problems.

pharmacist if:

pressure.

caused by cigarette smoking.

heart problem (including an uneven heart beat, a very fast pulse, narrowing of the arteries or heart failure).

You have problems with your thyroid or adrenal glands.

You have low levels of potassium in your blood.

- **Taking other medicines**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 taking any of the following medicines:

Beta-blocker medicines (such as atenolol or

propranolol for high blood pressure), including eyedrops (such as timolol for glaucoma).

Medicines for a fast or uneven heart beat (such as 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

- Steroid medicines that you take by mouth (such as prednisolone).

 Xanthine medicines (such as theophylline or
- aminophylline). These are often used to treat asthma.

 Other bronchodilators (such as salbutamol).

 Tricyclic anti-depressants (such as amitriptyline) and

the anti-depressant nefazodone.

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,
- itraconazole, voriconazole, posaconazole, clarithromycin and telithromycin).

 Medicines for Parkinson's disease (such as leva-dopa).
- 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.

 Pregnancy and breast-feeding

If you are pregnant, or planning to get pregnant, talk

- to your doctor before using Symbicort Turbohaler do 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

ability to drive or to use tools or machines.

- Important information about some of the
- 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 the time.
- 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
- 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 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,

symptoms may be improving. You might experience

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 Symbicort Turbohaler.

Your doctor may consider adding steroid tablets to your usual treatment during periods of stress (for example,

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 as possible, as you may need additional treatment. Contact your doctor immediately if:

Your breathing is getting worse or you often wake up

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

Important information about your asthma or COPD

at night with asthma.
Your chest starts to feel tight in the morning or your chest tightness lasts longer than usual.
These signs could mean that your asthma or COPD

These signs could mean that your asthma or COPD is not being properly controlled and you may need different or additional treatment immediately.

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

prescribed for you.

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 reliever inhaler'.

as your only inhaler, read the section called 'b) Using

b) If you have been prescribed Symbicort Turbohaler

a) Using Symbicort Turbohaler and a separate reliever inhaler
Use your Symbicort Turbohaler every day. This

helps to prevent asthma symptoms from happening.

The usual dose is 1 or 2 inhalations, twice a day.

Adults (18 years and above)

Symbicort Turbohaler as your only asthma inhaler'.

twice a day.

If your symptoms are well controlled, your doctor may ask you to take your medicine once a day.

Your doctor may increase this to 4 inhalations,

Adolescents (12 to 17 years)
The usual dose is 1 or 2 inhalations, twice a day.
If your symptoms are well controlled, your doctor

 If your symptoms are well controlled, your doctor may ask you to take your medicine once a day.
 A lower strength of Symbicort Turbohaler is available

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 asthma. They will adjust the dose of this medicine to the lowest dose that controls your asthma. However, do not adjust the dose without talking to your doctor (or asthma nurse) first.

Use your separate 'reliever inhaler' to treat asthma

Your doctor (or asthma nurse) will help you to manage

symptoms when they happen. Always keep your 'reliever inhaler' with you to use when you need it.
Do not use Symbicort Turbohaler to treat asthma symptoms - use your reliever inhaler.
b)Using Symbicort Turbohaler as your only asthma inhaler

Only use Symbicort Turbohaler in this way if your

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 evening

doctor has told you to and if you are aged 18 or above.

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.

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
- 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.

5. Place the mouthpiece gently between

your teeth. Close your lips. Breathe in

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

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.

intervals of 10 doses. Therefore it does

The dose indicator is marked in

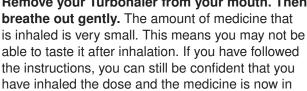
both directions.

How to take an inhalation

you need to use it. 4. Hold your Turbohaler away from your mouth. Breathe out gently (as far as is comfortable). Do not breathe out through your Turbohaler.

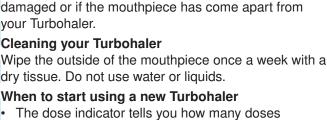
and ready to use. Only load your Turbohaler when

as deeply and as hard as you can through your mouth. Do not chew or bite on the mouthpiece. 6. Remove your Turbohaler from your mouth. Then



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 be taken off. Do not use your Turbohaler if it has been

7. If you are to take a second inhalation, repeat



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.

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

The most common symptoms that may occur if you

use more Symbicort Turbohaler than you should are

trembling, headache or a rapid heart beat.

product, ask your doctor or pharmacist.

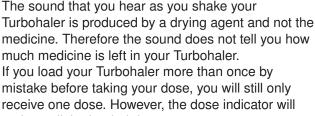
You should not exceed your prescribed dose without

register all the loaded doses.

seeking medical advice.

forgotten dose.

immediately:



If you use more Symbicort Turbohaler than you should It is important that you take your dose as stated on

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 dose, skip the missed dose. Do not take a double dose to make up for a

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

If you have any further questions on the use of this

hives together with difficulty breathing (angioedema) and/or sudden feeling of faintness. This may mean that you are having an allergic reaction. This happens rarely, affecting less than 1 in 1,000 people.

your 'reliever' inhaler. Contact your doctor immediately as you may need to have your treatment changed. This happens very rarely,

affecting less than 1 in 10,000 people.

Sudden acute wheezing or shortness of breath immediately after using your inhaler. If either of these symptoms occur, stop using your

- Symbicort Turbohaler and talk to your doctor Swelling of your face, particularly around your mouth (tongue and/or throat and/or difficulty swallowing) or
 - Symbicort Turbohaler straightaway and use

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.

- Nausea (feeling sick). Fast heart beat. Bruising of the skin.
- Muscle cramps. Rare (affects less than 1 in 1,000 people) Rash, itching.

Feeling dizzy.

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

Depression.

adolescents

comes on suddenly after using Symbicort Turbohaler

stop using Symbicort Turbohaler and talk to your doctor immediately.

Low levels of potassium in your blood. Uneven heart beat. Very rare (affects less than 1 in 10,000 people)

Changes in behaviour, especially in children. Chest pain or tightness in the chest (angina pectoris). An increase in the amount of sugar (glucose) in

- your blood. Taste changes, such as an unpleasant taste in the mouth.
- 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)

glaucoma (increased pressure in the eye)

a slowing of the rate of growth of children and

the kidney). These effects are much less likely to happen with inhaled corticosteroids than with corticosteroid tablets.

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

If any of the side effects get serious or if you notice

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

Do not use the inhaler after the expiry date that is

6. Further information What Symbicort Turbohaler 200/6 contains

fumarate dihydrate. Each inhaled dose contains

The active substances are budesonide and formoterol

What Symbicort Turbohaler 200/6 looks like and

Symbicort Turbohaler 200/6 is an inhaler containing

your medicine. The inhalation powder is white in colour.

Each Turbohaler contains either 60 or 120 doses and

measures will help to protect the environment.

dispose of medicines no longer required. These

200 micrograms of budesonide and 6 micrograms of formoterol fumarate dihydrate. The other ingredient is lactose monohydrate (which contains milk proteins).

has a white body with a red turning grip. The turning grip contains a Braille code with the number 6 for identification, to differ from other AstraZeneca inhaled products.

contents of the pack

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

AstraZeneca AB, S-151 85 Södertälje, Sweden.

Symbicort Turbohaler is authorised in the Member

States of the EEA under the following names: Symbicort Turbohaler and Symbicort Turbuhaler. In some countries, the dosage strength refers to the metered dose (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.

This leaflet was last approved in October 2011 © AstraZeneca 2011 Symbicort and Turbohaler are trade marks of the AstraZeneca group of companies. RSP 11 0190

AstraZeneca 🕏