

BIRESP® SPIROMAX®

Powder for Inhalation

Budesonide and formoterol (eformoterol) fumarate dihydrate

Consumer Medicine Information

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using BIRESP SPIROMAX?

BIRESP SPIROMAX contains two active ingredients in one inhaler: budesonide and formoterol (eformoterol) fumarate dihydrate. It is inhaled into the lungs for the treatment of asthma or Chronic Obstructive Pulmonary Disease (COPD).

For more information, see Section 1. Why am I using BIRESP SPIROMAX? in the full CMI.

2. What should I know before I use BIRESP SPIROMAX?

Do not use if you have ever had an allergic reaction to any medicine containing formoterol or budesonide or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use BIRESP SPIROMAX? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with BIRESP SPIROMAX and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use BIRESP SPIROMAX?

- **ASTHMA - Anti-inflammatory reliever only (BIRESP SPIROMAX 200/6)** - If you get asthma symptoms, take 1 inhalation and wait a few minutes. If you do not feel better, take another inhalation.
- **ASTHMA - Anti-inflammatory reliever plus maintenance therapy (BIRESP SPIROMAX 200/6)** – See above for reliever instructions. The usual maintenance dose is 2 inhalations per day (given either as 1 inhalation in the morning and evening or as 2 inhalations in either the morning or evening).
- **ASTHMA - Daily fixed dose maintenance therapy (BIRESP SPIROMAX 200/6 and 400/12)** – BIRESP SPIROMAX 200/6 usual dose is 1-2 inhalations twice a day. BIRESP SPIROMAX 400/12 usual dose is 2 inhalations twice a day.
- **COPD - The usual dose is 2 inhalations of BIRESP SPIROMAX 200/6 twice daily**

or 1 inhalation of BIRESP SPIROMAX 400/12 twice daily.

- Each pack of BIRESP SPIROMAX contains an instruction leaflet that tells you the correct way to use the device

More instructions can be found in Section 4. How do I use BIRESP SPIROMAX? in the full CMI.