Proposed Patient Information Leaflet Information

for the Patient about

BUDEFLAM 100 / 200 (METERED DOSE

INHALER)

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

BUDEFLAM 100 containing 100 µg **budesonide** (Metered dose inhaler)

BUDEFLAM 200 containing 200 µg **budesonide** (Metered dose inhaler)

Read all of this leaflet carefully before you start using BUDEFLAM:

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

WHAT BUDEFLAM CONTAINS:

The active ingredient in **BUDEFLAM** is budesonide.

BUDEFLAM 100: Each actuation (metered dose) delivers 100 µg budesonide.

BUDEFLAM 200: Each actuation (metered dose) delivers 200 µg budesonide.

Both inhalers also contain the CFC-free propellant 1,1,1,2-tetrafluoroethane (HFC-134a).

WHAT BUDEFLAM IS USED FOR:

BUDEFLAM belongs to a class of medicines called inhaled glucocorticosteroids (or steroids for short). **BUDEFLAM** reduces inflammation in the lungs and is used to prevent symptoms of asthma.

BEFORE YOU USE BUDEFLAM:

Do not use BUDEFLAM:

- If you are allergic (hypersensitive) to budesonide or any of the other components of **BUDEFLAM**.
- If you have been diagnosed with tuberculosis (TB) of the lungs.
- If you are coughing with the production of yellow, green or brown phlegm (mucus), or if you suffer from fever or chills.

Take special care with BUDEFLAM:

It is important that you use your **BUDEFLAM** inhaler correctly to ensure that the medicine reaches your lungs in sufficient amounts (see **"HOW TO USE BUDEFLAM"**). If you struggle with the technique, please ask your doctor, pharmacist or other healthcare professional for guidance.

BUDEFLAM is a long-term preventative medicine and you should continue to use your **BUDEFLAM** inhaler even if your chest feels open and you do not have wheezing or shortness of breath.

BUDEFLAM is not intended for rapid relief of sudden (acute) episodes of asthma. If you experience wheezing or tightness of the chest, you should use

your short-acting asthma (‘rescue’) inhaler. You must have your ‘rescue’ inhaler with you at all times.

Please inform your doctor if your ‘rescue’ asthma inhaler is no longer effective or becomes less effective, if you need more inhalations than usual or if your tight chess or shortness of breath persist.

If you experience an immediate increase in wheezing and shortness of breath after using **BUDEFLAM** (see **"POSSIBLE SIDE-EFFECTS"**), you must stop using **BUDEFLAM** immediately and use your rapid-acting ‘rescue’ inhaler. You should report to your doctor immediately.

Use of **BUDEFLAM** may cause infections of the mouth or throat giving rise to ulcers or white spots (or membranes) inside the mouth (see **"POSSIBLE SIDE-EFFECTS"**). If you previously had a yeast infection of the mouth presenting with white spots or white membranes inside the mouth, you are more likely to develop this side-effect. You may find it helpful to rinse your mouth thoroughly with water after using your **BUDEFLAM** inhaler. Do not swallow the water used to rinse your mouth (see **"HOW TO USE BUDEFLAM"**). Please report to your doctor as soon as possible if you notice ulcers or white spots inside your mouth, or if you experience burning or stinging when eating. In some instances your doctor may advise that you use a spacer device to help prevent such infections from recurring.

If you have been taking oral glucocorticosteroid medicines (such as prednisone)

to treat your asthma, your doctor may switch you to **BUDEFLAM** inhaler and stop your oral medicines. This transition demands special care, and your doctor will transfer you when your asthma is in a relatively stable phase. You should follow your doctor’s directions carefully. This transition may take some time and in some instances you may have to take additional oral medication. If you feel unwell or uneasy during this time, do not stop using **BUDEFLAM** inhaler, but ask your doctor for advice. Please inform your doctor as soon as possible if you experience a combination of poor appetite, stomach pain, weight loss, tiredness, or headache.

If you have been taking oral steroids for some time, or if you have been using high doses of **BUDEFLAM** for some time, it may be necessary to go for blood tests to monitor the function of your adrenal gland. You may also have to wear a steroid warning card to alert healthcare personnel that you may require additional oral steroid medication during illness (including infection), injury, or after surgery.

If you experience worsening of your asthma with the production of phlegm or mucus, please inform your doctor as soon as possible. You may require additional medication, such as antibiotics or oral steroids.

Do not stop using **BUDEFLAM** abruptly without discussing it with your doctor (see **"Effects when treatment with BUDEFLAM is stopped"**). If, for some reason, you are unable to use your **BUDEFLAM** inhaler and you develop loss of appetite, stomach pain, weight loss, tiredness, headache, nausea, vomiting, sleepiness or inattention, dizziness or light-headedness, or seizures

(convulsions), inform your doctor immediately.

If your doctor is switching you from oral steroid medicines to **BUDEFLAM** inhaler, please inform your doctor as soon as possible if you experience muscle or joint pain, skin rash, or runny or blocked nose.

Please inform your doctor as soon as possible if you notice any of the following side-effects:

- Weight gain with fat accumulating in the stomach area, the face, and between the shoulders accompanied by stretch marks, easy bruising, and sometimes acne.
- Slow growth in children or adolescents. Children who use **BUDEFLAM** for long periods of time have to go for regular check-ups to monitor their height.
- Poor or decreased vision.
- Increased susceptibility to infections.
- Poor wound healing.

You will have to go for regular check-ups with your doctor who will, amongst others, monitor your adrenal gland function. Long-term use of high doses of **BUDEFLAM** may cause brittleness of your bones.

Please inform your doctor if you have been diagnosed with poor or reduced liver function, because your doctor may need to monitor you for side-effects while you are using **BUDEFLAM**.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please discuss the use of **BUDEFLAM** with your doctor, as safety has not been established.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using BUDEFLAM.

Driving and using machinery:

BUDEFLAM has no or negligible influence on the ability to drive and use machines.

Taking other medicines with BUDEFLAM:

Always tell your healthcare professional if you are taking any other medicine.

If you are currently taking any of the following medicines, please discuss their use with your doctor or pharmacist:

- Ketoconazole or itraconazole for the treatment of fungal infections, since these medicines may increase blood levels, and therefore side-effects, of **BUDEFLAM**.

HOW TO USE BUDEFLAM:

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

Always use BUDEFLAM exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

SHAKE BEFORE USE. FOR ORAL INHALATION ONLY.

Adults and children over 12 years of age:

Your doctor will prescribe how many **BUDEFLAM** inhalations you must take per day. Usually the starting dose is 400 µg (4 inhalations of **BUDEFLAM 100** or 2 inhalations of **BUDEFLAM 200**) daily in divided doses.

Please report to your doctor if your asthma symptoms are not under control.

Children (5 years and older):

Your doctor will prescribe how many **BUDEFLAM** inhalations your child must take per day. The usual dose is 100 – 200 µg (1 – 2 inhalations of **BUDEFLAM 100** or 1 inhalation of **BUDEFLAM 200**) twice daily. Please report to your doctor if your child's asthma is not under control.

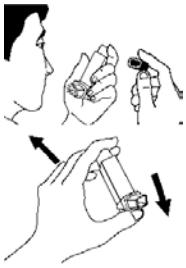
Instructions for the correct use of BUDEFLAM:

Note: It is important to:

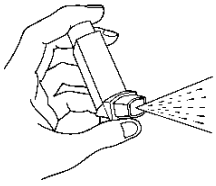
1. Carefully read the detailed instructions below.
2. Take your time when using the inhaler and not to rush through the individual steps.
3. Practise using the inhaler in front of a mirror. If you see any mist coming from the top of the inhaler or from the mouthpiece, it may mean that you have not inhaled the medicine properly.



4. Remove the mouthpiece cover, and check the mouthpiece thoroughly to see that it is clean. Shake the inhaler thoroughly for a few seconds to mix the contents of the inhaler properly.



5. Prime the inhaler by actuating/pressing it twice into the air when the inhaler is new, if it has been dropped, or when it has not been used for more than 7 days.



6. Hold the **BUDEFLAM** inhaler as shown between your index finger and thumb. Breathe out fully through your mouth and immediately place the mouthpiece in your mouth between your teeth (do not bite it).



7. Grip the mouthpiece firmly with your lips. Tilt your head slightly

backwards. Start breathing in slowly through your mouth. At the same time, press the canister as shown to release one dose while continuing to breathe in steadily and deeply. You may need to use both hands to operate the inhaler.

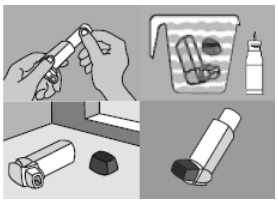


8. Remove the **BUDEFLAM** inhaler from your mouth. Continue to breathe in and hold your breath for as long as is comfortable. You must not breathe out through the inhaler.



9. Wait for about half a minute if a second or subsequent actuation/inhalation is required and then replace the mouthpiece in your mouth and repeat steps 6, 7 and 8.
10. Rinse your mouth out with water after inhaling the prescribed dose of **BUDEFLAM** to minimise the risk of developing thrush (yeast infection) of your mouth or throat.
11. Clean the mouthpiece of your **BUDEFLAM** inhaler regularly, at least once a week. Remove the mouthpiece cover and gently pull the metal canister out of the **BUDEFLAM** inhaler. Clean the plastic actuator and mouthpiece cover with a dry cloth or tissue. Do **NOT** put the metal canister into water

or clean it with water.



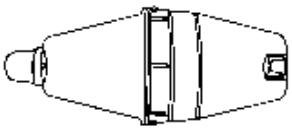
If you are using other inhalers, such as inhaled bronchodilators (a ‘rescue’ inhaler), you should use the bronchodilator several minutes before inhaling **BUDEFLAM** to minimise possible side-effects, such as cough.

For children:

Young children may need help. To help your child, you must first learn the technique correctly yourself and then properly guide your child to use the **BUDEFLAM** inhaler (also see **"Using a spacer device"**).



Using a spacer device:



The use of a spacer device is recommended when the daily **BUDEFLAM** dose exceeds 400 µg (4 inhalations of **BUDEFLAM 100** or 2 inhalations of **BUDEFLAM 200**) in adults and for all doses in children. This will improve lung deposition and will reduce the side-effects of **BUDEFLAM**.

BUDEFLAM is long-term (chronic) medicine and you should not stop treatment with **BUDEFLAM** abruptly (see **"Take special care with BUDEFLAM"**). You must continue your treatment with **BUDEFLAM** even if your asthma symptoms are under control. Your doctor will tell you how long treatment with **BUDEFLAM** will last.

If you have the impression that the effect of **BUDEFLAM** is too strong or too weak, tell your doctor or pharmacist.

If you use more BUDEFLAM than you should:

If you use more **BUDEFLAM** than you should, you may require blood tests to monitor the function of your adrenal glands (see **"Take special care with BUDEFLAM"**). **In the event of overdosage, consult your doctor or pharmacist immediately. If neither is available, seek help at the nearest hospital or poison control centre.**

If you forget to use BUDEFLAM:

Always use **BUDEFLAM** as directed. If you miss a dose, use **BUDEFLAM** as soon as possible. However, if you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not use a double dose to compensate for the forgotten individual dose.

Effects when treatment with BUDEFLAM is stopped:

Do NOT stop **BUDEFLAM** treatment abruptly, because your adrenal glands may

need time to adjust to the absence of the medicine. Your doctor may need to reduce your **BUDEFLAM** dose over a period of time before you stop **BUDEFLAM** treatment.

POSSIBLE SIDE-EFFECTS:

BUDEFLAM can have side-effects.

Not all side-effects reported for BUDEFLAM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using BUDEFLAM, please consult your doctor, pharmacist or other healthcare professional for advice.

Serious side-effects that you should report to your doctor as a matter of urgency include:

- Those that occur frequently:
    - Acting strangely or inappropriately.
    - Unexpected constriction of the airways with wheezing or tightness of the chest (see **"Take special care with BUDEFLAM"**).
    - Coughing accompanied by fever, shortness of breath and difficult breathing (see **"Take special care with BUDEFLAM"**).
- Those that occur less frequently:
    - Allergic reactions, including rash, itching, hives, swelling of the tongue, lips or face, tightness of the chest, and wheezing or difficult breathing.
    - Purple spots or patches on the skin.

Other side-effects that you should report to your doctor as soon as possible include:

- Those that occur frequently:
    - White spots, white membranes or ulcers in the mouth or throat (see **"Take special care with BUDEFLAM"**).
    - Skin thinning.
- Those that occur less frequently:
    - Slowed growth in children (see **"Take special care with BUDEFLAM"**).
    - Depression, behavioural disturbances.
    - Poor or reduced vision.

Please report the following side-effects to your doctor or pharmacist if they continue or become bothersome:

- Those that occur frequently:
    - Tingling sensation in the throat with slight coughing, hoarseness, or mild throat irritation.
    - Dryness of mouth and throat, bad taste.
- Those that occur less frequently:
    - Nervousness, restlessness.
    - Headache.
    - Nausea and diarrhoea (loose stools).
    - Tiredness and thirst.

If you notice any side-effects not mentioned in this leaflet, please inform your

doctor or pharmacist.

STORING AND DISPOSING OF BUDEFLAM:

Store at or below 30 °C.

Avoid storage in direct sunlight or heat. The canister should not be punctured, broken or burnt even if it is apparently empty.

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist.

PRESENTATION OF BUDEFLAM:

BUDEFLAM 100: A seamless aluminium canister with a metered dispensing valve crimped in place and a mouthpiece attached. Each canister provides 300 metered inhalations.

BUDEFLAM 200: A seamless aluminium canister with a metered dispensing valve crimped in place and a mouthpiece attached. Each canister provides 300 metered inhalations.

IDENTIFICATION OF BUDEFLAM:

BUDEFLAM 100: A milky white homogeneous suspension filled in an aluminium container in CFC-free propellant gas.

BUDEFLAM 200: A milky white homogeneous suspension filled in an aluminium container in CFC-free propellant gas.

REGISTRATION NUMBERS:

BUDEFLAM 100: 30/21.5.1/0255

BUDEFLAM 200: 32/21.5.1/0115

NAME AND BUSINESS ADDRESS OF THE HOLDER CERTIFICATES OF REGISTRATION:

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DATE OF PUBLICATION OF THIS PATIENT LEAFLET:

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