Clenil® 250mcg

pressurised inhalation solution
beclomethasone dipropionate

COMPOSITION
Each canister contains:
Active ingredient:
Beclomethasone-dipropionate 50 mg (each actuation delivers 250 micrograms)
Excipients: HFA 134a (norflurane), ethanol, glycerol.

Pressurised canister providing 200 inhalations of 250 micrograms of beclomethasone.
The product does not contain any substance damaging ozone.

THERAPEUTIC INDICATIONS
Control of asthmatic disease development and of bronchostenotic conditions in those patients who do not obtain a satisfactory control of symptoms with the usual inhaled doses of beclomethasone dipropionate.

CONTRAINDICATIONS
Tubercular (active or quiescent) and local viral infections. Individual hypersensitivity to cortisonics.
Usually contraindicated in pregnancy and lactation (see Special warnings)

PRECAUTIONS FOR USE
Patients should be properly instructed about the correct use of the inhaler.
The management of treatment in patients already undergoing systemic corticotherapy, needs special precautions and a strict medical control since the reactivation of adrenal function, suppressed by the prolonged systemic corticosteroidal therapy, is slow. In any case, it is necessary that the disease be relatively stabilised by the systemic treatment. At the beginning, CLENIL® should be administered while continuing the systemic therapy; then, this should be gradually reduced checking the patient regularly (in particular, periodical tests of corticoadrenal function should be carried out) and modifying CLENIL® posology according to the results obtained. During periods of stress or of severe asthmatic attacks, patients undergoing this passage shall be supported by a supplemental treatment with systemic steroids. CLENIL® is not effective in asthmatic attack in progress; on the contrary, it represents an essential treatment of the asthmatic disease, therefore it should be regularly taken at the prescribed doses and as long as the physician deems it as suitable. Patients should be duly informed that the product contains small amounts of ethanol and glycerol. These quantities are negligible and do not constitute a risk for patients with the usually administered therapeutic doses. However, due to the presence of alcohol, the product should be cautiously used in patients suffering from hepatic pathologies, alcoholism (see also Interactions), epilepsy, cerebral pathologies.

INTERACTIONS
CLENIL® contains a small amount of ethanol. There is the theoretical potential for interaction in particularly sensitive patients taking disulfiram or metronidazole.

SPECIAL WARNINGS
CLENIL® is not efficacious in asthma attacks in progress; on the contrary, it represents a fundamental treatment of the asthmatic disease: it should be regularly taken at the prescribed doses and as long as the physician deems it as suitable.
Pregnancy and lactation. In pregnant women the product should be administered in case of real need and under direct medical control. There is inadequate evidence of safety of beclomethasone dipropionate or HFA 134a propellant in humans. Product administration during pregnancy and lactation should be only taken into consideration if the envisaged benefit for the mother outweighs the potential risks for the foetus.
Children born from mothers having received considerable doses of inhaled corticosteroids during pregnancy, should be carefully monitored in order to detect a possible hypoadrenalism.
Studies on the effects of the propellant HFA 134a on reproductive function and embryofoetal development in animals did not point out clinically important adverse events. Therefore, the occurrence of adverse events in humans is unlikely.

POSOLOGY, METHOD AND FREQUENCY OF ADMINISTRATION
Adults : usually, 2 inhalations twice a day. Should it be deemed as more suitable, posology can be fractioned even into 1 inhalation 4 times daily. In case of need, therapy can be increased up to 2 inhalations 3-4 times a day.
Therapy with CLENIL® should not be abruptly interrupted
Children: CLENIL® 250mcg is not suitable for pediatric use.

Instructions for use
The successful result of the treatment depends on a correct use of the inhaler.
Inhaler's working test: before using the inhaler for the first time or if it has not been used for three days or more, remove the mouthpiece protective closure by softly pressing it on its sides and press once in the air to release an actuation, so as to verify the correct working of the inhaler.
For use, carefully follow the following instructions:

1) hold the actuator between thumb and index, with the mouthpiece downwards;
2) remove the protecting cap;
3) place the mouthpiece firmly between the lips and make a complete expiration;
4) make a long and deep inspiration with the mouth only and, at the same time press once only with the index.

Once the inspiration is complete, hold breath as long as possible.
When inhalations are completed, close the mouthpiece again with the protecting cap. The mouthpiece should always be kept clean. Cleaning should be made with lukewarm water, after having extracted the pressurised canister.

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UNDESIRABLE EFFECTS
Occasionally, local mycotic infections (candidiasis) can appear in the oropharyngeal cavity, usually rapidly regressing after local antimycotic therapy and without interrupting the treatment. The occurrence of these mycotic infections can be reduced to the minimum by regularly rinsing the mouth after every application.
A few patients complained about hoarseness and dry mouth.
Systemic side effects are extremely improbable with the recommended doses; however, patients should be kept under strict control during prolonged treatments, in order to timely ascertain the possible occurrence of systemic diseases (osteoporosis, peptic ulcer, signs of secondary corticoadrenal insufficiency, such as hypotension and weight loss) and in order to avoid, in this latter event, very serious accidents due to acute hypoadrenalism. Inhalation of high doses (> 1500 mcg/day) for prolonged periods may cause adrenal suppression. As with other inhalation therapy paradoxical bronchospasm may occur.

The observance of the instructions contained in the present package insert reduces the risk of undesirable effects.
It is important to promptly inform the physician or chemist about any undesirable effect, even if not reported in this leaflet.

EXPIRY DATE AND STORAGE
See the expiry date reported on the box; this date is intended for the unopened and correctly stored product.

ATTENTION: do not use the medicinal product when the indicated date is expired.

PRECAUTIONS FOR STORAGE
The pressurised container should not be pierced and should be protected from heating sources, even when apparently empty. It must neither be frozen nor exposed to direct sunlight. Store below 30°C.

Keep out of the reach of children

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Chiesi

CHIESI FARMACEUTICI S.p.A. *- Via Palermo, 26/A - Parma* *OFFICINE di PARMA* 87D35.03/01

کلینیل 250 مائیکروگرام

بیکلومیتھازون ڈائی پروپیونیٹ۔ سانس کے ذریعے کھینچنے والا محلول۔

اجزائے ترکیبی اور وضاحت:

ہر کینسٹر (Canister) میں بیکلومیتھازون ڈائی پروپیونیٹ 50 ملی گرام بطور عامل جز شامل ہے۔ ہر شش (Puff) میں 250 مائیکروگرام بیکلومیتھازون ڈائی پروپیونیٹ اخراج ہے۔

ہر کینسٹر (Canister) بیکلومیتھازون ڈائی پروپیونیٹ کے 200 شش (خوراکیں) مہیا کرتا ہے۔

کلینیل 250 میں شامل تمام اجزا مکمل طور پر ماحول دوست ہیں۔

علامات:

دمہ کو مزید بڑھنے اور سانس کی تنگ نالیوں پر قابو پانے کیلئے۔ ایسے مریض جو سانس کے ذریعے کھینچنے والی بیکلومیتھازون ڈائی پروپیونیٹ کی عمومی خوراک سے دمہ کی علامات پر تسلی بخش قابو نہ پا سکیں۔

ممانعت برائے علاج:

ایسے مریض جن کو اسٹیرائیڈز سے ذو حسی (Hypersensitivity) ہو۔ ایسے مریض جن کو شدید یا عمومی ہیپھڑوں کی ٹی بی ہو۔

حاملہ اور دودھ پلانے والی خواتین اپنے معالج کی زیر نگرانی صرف انتہائی ضرورت کے تحت دوا استعمال کر سکتی ہیں۔

خوراک اور طریقہ استعمال:

بڑوں کیلئے:

عموماً 2 شش (Puff) دن میں دو مرتبہ۔ بہتری کی صورت میں ایک شش (Puff) دن میں چار مرتبہ بھی لیا جا سکتا ہے۔

دوائی کی زیادہ مقدار مطلوب ہونے کی صورت میں 2 شش (Puff) دن میں 3-4 مرتبہ بڑھائے جا سکتے ہیں۔

بچوں کیلئے:

بچوں میں کلینیل 250 کا استعمال مناسب نہیں ہے۔

طریقہ استعمال:

علاج کے کامیاب نتائج دم شش **(Inhaler)** کے درست طریقہ استعمال پر منحصر ہیں۔

انہیلر ٹیسٹ: نئے دم شش (Inhaler) کو استعمال کرنے سے پہلے۔ (یا اگر انہیلر کو استعمال کئے ہوئے 3 یا اس سے زیادہ دن ہو چکے ہوں) تو انہیلر (Inhaler) ٹیسٹ ضرور کریں۔

منہ میں لینے والے حصے (Mouth Piece) کے اوپر لگے حفاظتی ڈھکن کو دونوں اطراف نرمی سے دباتے ہوئے ہٹائیں اور ہوا میں ایک شش (Puff) نکالیں۔ تاکہ اس کے درست کام کرنے کی تصدیق ہو جائے۔

استعمال سے پہلے نیچے دی گئی ہدایات کو غور سے پڑھ لیں:

(1-2) منہ میں لینے والے حصے (Mouth Piece) کو نیچے کی طرف رکھتے ہوئے دم شش کو انگوٹھے اور شہادت کی انگلی کے درمیان پکڑیں جیسا تصویر میں دکھایا گیا ہے۔ منہ میں لینے والے حصے کا ڈھکن ہٹا لیں۔

(3) سانس کو مکمل باہر نکالیں اور منہ میں لینے والے حصے (Mouth Piece) کو منہ میں رکھیں اور اپنے ہونٹوں کو مضبوطی سے اس کے گرد بند کر لیں۔

(4) ایک دفعہ شہادت کی انگلی سے کینسٹر (Canister) کو دبائیں اور سانس منہ کے راستے اندر کھینچیں۔

جب سانس کو اندر کھینچنے کا عمل مکمل ہو جائے تو جتنی زیادہ دیر تک سانس کو روک سکتے ہیں روکے رکھیں۔ جب یہ عمل مکمل ہو جائے تو منہ میں لینے والے حصے (Mouth Piece) کو ہٹا کر حفاظتی ڈھکن سے بند کر دیں۔ دم شش (Inhaler) کو ہمیشہ صاف رکھیں۔ صاف کرنے کیلئے کینسٹر (Canister) کو پلاسٹک کے خول سے باہر نکالیں اور نیم گرم پانی سے دھو کر کینسٹر (Canister) کو دوبارہ پلاسٹک کے خول میں لگا دیں۔

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

صرف مستند ڈاکٹر کے نسخہ کے مطابق ہی دوا فروخت کی جائے۔

تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

دوا کو 30°C سے کم درجہ حرارت پر، بچی اور روشنی سے محفوظ رکھیں۔

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