SUMMARY OF PRODUCT CHARACTERISTICS

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

1 NAME OF THE MEDICINAL PRODUCT

Diethylpropion Hydrochloride 25mg
Pharmaceutical Form: Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Table: Diethylpropion hydrochloride 25mg, Lactose 130mg
For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Pink, slightly speckled, round coded “DPY 25” tablets with a breakline on one side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

As an anorectic agent for short term use as an adjunct to the treatment of some patients with moderate to severe obesity and a body mass index (BMI) of 30kg/m2 or higher, who have not responded to an appropriate weight-reducing regimen alone and for whom close support and supervision are also provided.

Note: short-term efficacy only has been demonstrated with regard to weight reduction. No significant data on changes in morbidity are yet available.
4.2 Posology and method of administration

For oral administration only.

Adults:
It is recommended that treatment be conducted under the care of physicians experienced in the treatment of obesity.
Organic causes of obesity should be investigated and excluded by diagnosis before prescribing diethylpropion.
An appropriate approach to obesity management should include dietary and behavioural modification as well as increased physical activity. This integrated approach is essential for a lasting change in eating habits and behaviour which is fundamental to the long-term maintenance of the reduced weight level once diethylpropion is stopped. Patients should change their lifestyle while on diethylpropion so that they are able to maintain their weight once drug treatment has ceased. They should be informed that, if they fail to do so, they may regain weight. Even after cessation of diethylpropion, continued monitoring of the patient by the physician should be encouraged.
The dose is 25mg twice or three times daily one hour before meals. Evening doses should be avoided. The recommended dosage should not be exceeded. The duration of treatment is 4-6 weeks and should not exceed three months. Intermittent dosage consisting of treatment for four to six weeks, followed by a similar period without medication may be as effective as continuous treatment and may reduce the risk of dependence. Administration should not continue if weight loss does not occur or ceases.

Elderly:
Not recommended.

Children:
Not recommended.

4.3 Contraindications

- Known hypersensitivity to diethylpropion or to any of the excipients.
- Sensitivity to sympathomimetic agents.
• Organic causes of obesity.

• Concurrent use with other appetite suppressants.

• Emotionally unstable patients, and patients with a current or past history of psychiatric disorders including anorexia nervosa and depression.

• History of drug or alcohol abuse.

• Pulmonary artery hypertension, severe arterial hypertension, phaeochromocytoma, current or past history of cardiovascular or cerebrovascular disease.

• Hyperthyroidism.

• Narrow angle glaucoma.

• Concurrent use with therapies inhibiting monoamine oxidase (MAOIs) or within 14 days of stopping such treatment (see section 4.5).

• Pregnancy, women of childbearing potential not using contraception, and lactation (see section 4.6).

• Porphyria.

• Children below 12 years of age.

• Benign prostatic hyperplasia with urinary retention.

4.4 Special warnings and precautions for use

Cases of severe, often fatal, pulmonary artery hypertension have been reported in patients who have received anorectics of the type in this product. An epidemiological study has shown that anorectic intake is a risk factor involved in the development of pulmonary artery hypertension and that the use of anorectics is strongly associated with an increased risk for this adverse drug reaction. In view of this rare but serious risk, it must be emphasised that:

• Careful compliance with the indication and the duration of treatment is required.
• Duration of treatment greater than 3 months and a BMI > 30kg/m² increase the risk of pulmonary artery hypertension.

• The onset or aggravation of exertional dyspnoea suggests the possibility of occurrence of pulmonary artery hypertension. Under these circumstances treatment should be immediately discontinued and the patient referred to a specialist unit for investigation.

There are general concerns that certain anti-obesity drugs are associated with an increased risk of cardiac valvulopathy. However, clinical data show no evidence of an increased incidence with diethylpropion. Prolonged use of diethylpropion may give rise to pharmacological tolerance and may induce amphetamine-type dependence with the risk of social abuse for its euphoriant effect and a withdrawal syndrome on cessation of therapy. Several cases of toxic psychoses have been reported after excessive use of diethylpropion and a very small number have been reported in which the recommended dosage appears not to have been exceeded. The psychosis was temporary and cleared up when the drug was discontinued. Rarely cases of cardiac and cerebro-vascular incidents have been reported, often following rapid weight loss. Special care should be taken to ensure gradual and controlled weight loss in obese patients who are subject to a risk of vascular or cerebro-vascular disease. Use with caution in epileptic patients and in those with mild to moderate hypertension (see section 4.3). Diethylpropion, including illegally manufactured tablets has been the subject of social abuse for euphoriant effect. Patients with rare hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Care should be exercised when administered concurrently with antihypertensives, antidiabetic medication, psychotropic drugs, sedatives and other sympathomimetic agents. Alcoholic drink should be avoided.

To avoid precipitating a hypertensive crisis, diethylpropion should not be given to patients being treated with an MAOI or within 14 days of stopping such treatment (see section 4.3). Examples of MAOIs are moclobemide, seligiline, isoniazid, linezolid, phenelzine and tranylcypromine.
4.6 Pregnancy and lactation

There are no data for the use of diethylpropion in pregnant women. Studies in animals have shown reproductive toxicity. Diethylpropion is contraindicated during pregnancy and in women of childbearing potential not using contraception.

There is insufficient information on the excretion of diethylpropion or its metabolites in human milk so the risk to the suckling child cannot be excluded. Diethylpropion is contraindicated during breastfeeding.

4.7 Effects on ability to drive and use machines

Diethylpropion can have a major influence on the ability to drive or use machinery safely. Vertigo, convulsions and psychiatric reactions can occur, and withdrawal reactions can include rebound sedation. Patients must be informed of this and should refrain from driving or operating machines if affected.

4.8 Undesirable effects

<table>
<thead>
<tr>
<th>MedDRA system organ class</th>
<th>Adverse reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychiatric disorders</td>
<td>Psychosis, depression, nervousness, agitation, sleep disorders</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>Headache, paraesthesia, vertigo, convulsions</td>
</tr>
<tr>
<td>Cardiac disorders</td>
<td>Tachycardia, palpitations, hypertension, chest pain</td>
</tr>
<tr>
<td>Vascular disorders</td>
<td>Pulmonary artery hypertension (see note below)</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>Dry mouth, constipation, nausea, vomiting</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>Rashes, sweating</td>
</tr>
<tr>
<td>Reproductive system and breast disorders</td>
<td>Gynaecomastia</td>
</tr>
<tr>
<td>Other</td>
<td>Prolonged use is associated with a risk of pharmacological tolerance, dependence and withdrawal syndrome</td>
</tr>
</tbody>
</table>
Pulmonary artery hypertension

An epidemiological study has shown that anorectic intake is a risk factor involved in the development of pulmonary artery hypertension and that the use of anorectics is strongly associated with an increased risk for this adverse drug reaction. Cases of pulmonary artery hypertension have been reported in patients treated with this agent. Pulmonary artery hypertension is a severe and often fatal disease. The occurrence or aggravation of exertional dyspnoea is usually the first clinical sign and requires treatment discontinuation and investigation in a specialised unit.

Adverse reactions reported with other anorectic agents

Rarely cases of cardiovascular or cerebrovascular incidents have been described in patients with anorectic agents. In particular stroke, angina, myocardial infarction, cardiac failure and cardiac arrest have been reported.

Cardiac valvular disorders have also been seen in patients treated with other anorectic agents.

Reporting of suspect adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

4.9 Overdose

Symptoms

Central nervous system features of sympathomimetic overdose include agitation, confusion, hallucinations, ataxia, tremors and convulsions. Cardiovascular effects include tachycardia, arrhythmias and severe hypertension. Other features of sympathomimetic overdose include vomiting, diarrhoea, abdominal cramps, dilated pupils, hyperthermia, hypokalaemia and hyperglycaemia.

Treatment

The benefit of gastric decontamination is uncertain. Consider activated charcoal (50 g for adults; 1 g/kg for children) within 1 hour of a potentially life-threatening overdose. Treatment is largely symptomatic and includes sedation as required, with management of hypertension, arrhythmias and convulsions.
5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Sympathomimetic agent with anorectic properties.
The increased metabolic stimulation characteristic of sympathomimetic action is considered to play little part in the action of anorectic agents; their action depends mainly upon suppression of appetite, mediated possibly through the hypothalamus.

5.2 Pharmacokinetic properties

Diethylpropion is readily absorbed from the gastro-intestinal tract and is excreted in the urine. Many metabolites have been reported.

5.3 Preclinical safety data

No approved SPC for this product

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Dispersed Brown
Dispersed Pink
Magnesium Stearate
Tartaric Acid
Pregelatinised Starch

6.2 Incompatibilities

None
6.3 **Shelf life**

No approved SPC for this product
36 Months

6.4 **Special precautions for storage**

No approved SPC for this product
Store in a cool, dry place
Protect from light

6.5 **Nature and contents of container**

Tamper-proof container.
Contains 42, 50, 84, 100, 250, 500, 1000, 10000 tablets per tube.

6.6 **Special precautions for disposal**

No approved SPC for this product

7 **MARKETING AUTHORISATION HOLDER**

Essential Nutrition Ltd
Bank House
Saltgrounds Road
Brough
East Yorkshire
HU15 1EG
8 MARKETING AUTHORISATION NUMBER(S)

PL 16133/0001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORITY

18/11/2011

10 DATE OF REVISION OF THE TEXT

10/09/2014