Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Suscard Buccal Tablet 3 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 3 mg of glyceryl trinitrate as Diluted Nitroglycerin.

Also contains 37mg of lactose monohydrate

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged release Buccal Tablet.
White, biconvex, round tablets having the number '3' imprinted on one face.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the management and treatment of angina pectoris. This product may also be of benefit in the in-patient management of unstable angina.

For the treatment of acute and congestive cardiac failure.

4.2 Posology and method of administration

For adults (including the elderly)

Angina:
Administration of Suscard Tablets should start with the 2mg strength. If angina occurs while the tablet is in place, the dosage strength used should be increased to 3mg where necessary. The 5mg dosage strength should be reserved for patients with severe angina pectoris refractory to treatment with the lower dosage strengths. A 1 mg dosage strength is also available and may be considered for the small number of patients who may initially show intolerance to the 2 mg strength as a starting dose.

Suggested dosage frequency in angina:

a) For patients suffering only occasional angina pectoris – the tablets may be administered on a p.r.n. basis to relieve the acute attack.

b) For patients suffering angina pectoris in response to known stimuli - the tablet should be administered a few minutes prior to encountering the angina-precipitating stimulus.

c) For patients in whom chronic therapy is indicated - the tablet should be administered on a thrice-daily basis or as indicated by the dissolution rate of the tablet in an individual patient. If angina occurs during the period between the disappearance of one tablet and the time the next tablet is due to be put in place, dosage frequency should be increased.

Note: That if an acute attack of angina pectoris is suffered while a tablet is in place, an additional tablet may be positioned on the opposite side of the mouth.

Unstable Angina:
Dosage should be rapidly titrated upwards in order to relieve and prevent symptoms. Suscard Tablets may be used in addition to pre-existing anti-anginal therapy, where considered appropriate.

The 5mg dosage strength may be required to achieve a satisfactory therapeutic response in patients exhibiting severe symptoms. Unstable angina is a serious condition managed under hospitalised conditions and involving continuous monitoring of ECG changes with frequent monitoring of appropriate haemodynamic variables. In common with other nitrate therapy a fall in systolic blood pressure, of 10-15mm hg may occur.

Acute heart failure:
Administer 5mg, repeated as indicated by the patient response until the symptoms abate.

Congestive cardiac failure:
Dosage should commence with the 5mg strength, administered three times daily. In moderately severe or severe cases, particularly where patients have not responded to standard therapy (digitalis/diuretics), the dosage may need to be increased to 10mg (2 x 5mg tablets) t.i.d. over a period of three or four days. In such instances one tablet should be placed between the upper lip and the gum, on each side of the front teeth.

Method of Administration:
Buccal - The tablet is to be placed high up on the upper gum beneath the upper lip.

4.3 Contraindications

1. Use in patients with a known hypersensitivity to the nitrates.
2. This product should not be used in patients with severe anaemia, head trauma, cerebral haemorrhage or close angle glaucoma.
3. Suscard should not be co-administered with sildenafil.

4.4 Special warnings and precautions for use

1. Rarely prolonged use in susceptible individuals with poor dental hygiene and associated plaque may lead to an increased risk of dental caries. Patients should be instructed to alternate the site of application and pay careful attention to dental hygiene, particularly in those areas where the tablet is applied.

2. In conditions where xerostomia (dry mouth) may occur, e.g. during concomitant medication with drugs having anticholinergic effects, patients should be instructed to moisten the buccal mucosa with the tongue, or with a little water, prior to insertion of Suscard.

3. Headache may occur as a side effect and it is also a sign of overdose. Usually the headache subsides after a few days.

4. Toxic effects of glyceryl trinitrate including vomiting, restlessness, cyanosis, methaemoglobinaemia and syncope. In the event of problematic unwanted effects the tablet should be removed from the buccal pouch.

5. Hypotension may lead to cerebral ischaemia.

6. Prolonged and high dosage may induce methaemoglobinaemia.

7. Occasionally myocardial ischaemia may be aggravated in susceptible patients.

8. Nitrates may give rise to symptoms of collapse after the first dose in patients with labile circulation.

9. Experience has shown that Suscard may be used acutely concurrently with existing chronic nitrate therapies, e.g. transdermal or oral. Care should be taken to avoid excessive concurrent multiple nitrate therapy.

4.5 Interaction with other medicinal products and other forms of interaction

Some of the effects of alcohol and other vasodilators may be potentiated by this agent. In common with other nitric oxide donors, Suscard should not be co-administered with sildenafil as a significant fall in blood pressure may result.

4.6 Fertility, pregnancy and lactation

This product should not be used during pregnancy and in women breast feeding infants, unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

As for other drugs which produce changes in blood pressure, patients taking glyceryl trinitrate should be warned not to drive or operate machinery if they experience dizziness or related symptoms. This applies particularly when starting treatment, during uptitration, switching from another drug or starting a new co-medication and in conjunction with alcohol.

4.8 Undesirable effects

Side-effects are predominantly headache, dizziness, facial flushing and postural hypotension. In the unlikely event of severe side-effects, the tablet may simply be removed from the mouth.

4.9 Overdose

Toxic effects of glyceryl trinitrate include vomiting, restlessness, cyanosis, methaemoglobinaemia and syncope. Overdosage (i.e. if large numbers of tablets have been swallowed) should be treated with gastric aspiration and lavage plus attention to the respiratory and circulatory systems.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The principal action of glyceryl trinitrate is relaxation of vascular smooth muscle producing a vasodilator effect on both peripheral arteries and veins. Dilation of the post-capillary vessels, including large veins, promotes peripheral pooling of blood and decreases venous return to the heart, thereby reducing left ventricular end-diastolic pressure (preload). Arteriolar relaxation reduces systemic vascular resistance and arterial pressure (afterload). Myocardial oxygen consumption or demand for a given level of exercise is decreased by both the arterial and venous effects of nitroglycerin. Dilatation of the large epicardial coronary arteries by nitroglycerin contributes to the relief of exertional angina.

5.2 Pharmacokinetic properties

Bioavailability relative to sublingual GTN: 107%.

Mean plasma levels of 0.75ng/ml obtained with 5mg Buccal Tablet over 5 hours compared with 0.4ng/ml over 30 minutes with 0.4mg sublingual GTN.

Maximum plasma concentration: 1.7ng/ml following 5mg Buccal compared with 0.9ng/ml following 0.4mg sublingual GTN.

Time to maximum plasma concentration: 1.52 hours following Buccal GTN compared with 6 minutes following sublingual GTN.

Apparent elimination half-life: 1.30 hours for Buccal GTN compared with an elimination half-life of 5 minutes following sublingual GTN.

Pharmacodynamic studies have shown a dose-related response with a rapid onset equivalent to sublingual GTN, together with a prolonged duration of activity of 4-5 hours.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber that might add to the safety data already provided in other sections of this SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Hypromellose
Peppermint flavour
Spearmint flavour
Stearic acid
Silica gel

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and contents of container

Aluminium blister strips in packs of 10, 30, 50, 60, 90 and 100 tablets in a cardboard carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Forest Laboratories UK Limited
Riverbridge House
Anchor Boulevard
Crossways Business Park
Dartford
Kent
DA2 6SL

8 MARKETING AUTHORISATION NUMBER

PA 100/33/5

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28 August 1983

Date of last renewal: 28 August 2008

10 DATE OF REVISION OF THE TEXT

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