Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Mu-Cron Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Paracetamol	500 mg
Phenypropanolamine hydrochloride	25 mg

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film coated tablet
White capsule-shaped tablet, imprinted ‘Mu-Cron’ on one side with a scoreline on the other side.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an analgesic/antipyretic agent where a decongestant effect is also required.

4.2 Posology and method of administration

Adults:
One tablet up to four times daily with a minimum interval of 4 hours between doses. The maximum daily dose of four tablets should not be exceeded.

Children under 12 years:
Not recommended.

Route of administration:
Oral.

4.3 Contraindications

Use in patients hypersensitive to the active ingredient.

Use in patients with severe heart disease**,** including acute ischaemic heart disease, hypertension, hyperthyroidism, diabetes, glaucoma, urinary retention, high fever.

Use in patients who are currently receiving, or have within two weeks received, monoamine oxidase inhibitors or tricyclic antidepressants.
Use concurrently with other sympathomimetic agents.

4.4 Special warnings and precautions for use

Patients are advised to consult their doctor before taking Mu-Cron tablets if they are under the care of their doctor, receiving continual prescribed medication, pregnant or if their symptoms persist.

This product should be used with great care in patients suffering from angina. Patients with prostatic hypertrophy may have increased difficulty with micturition. This product may act as a cerebral stimulant giving rise to insomnia, nervousness, hyperpyrexia, tremor and epileptiform convulsions.

Special labelling requirements:

1. If you are taking medication or are under a doctor's care consult him before using.
2. Do not exceed the stated dose, an overdose is dangerous.
3. If symptoms persist, consult your doctor.
4. Prolonged use except under medical supervision may be harmful.

4.5 Interaction with other medicinal products and other forms of interaction

Mu-Cron may interact with monoamine oxidase inhibitors to produce a hypertensive crisis.

This product should be used with caution in patients receiving digitalis, beta-adrenergic blockers, guanethidine, reserpine, phenothiazines, tricyclic antidepressants or methyldopa or anti-hypertensive agents.

Concurrent use with halogenated anaesthetic agents such as chloroform, cyclopropane, halothane, enflurane and isoflurane may provoke or worsen ventricular arrhythmias.

The physician or pharmacist should reassure himself that sympathomimetic containing preparations are not simultaneously administered by several routes i.e. orally and topically (nasal, aural and eye preparations).

4.6 Pregnancy and lactation

The product should not be used in pregnancy unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

None stated.

4.9 Overdose

Overdose with Mu-Cron tablets should be immediately treated by inducing emesis and gastric lavage. Vital functions should be monitored and supported.

Symptoms of overdosage include: bradycardia, tachycardia, hypotension or hypertension, cardiac arrhythmias, circulatory collapse, cerebrovascular haemorrhage possibly associated with hypertensive crises.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Decongestant analgesic/antipyretic combination.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core
Acacia
Maize starch
Pre-gelatinised maize starch
Colloidal silica
Stearic acid
Magnesium stearate
Purified talc special
Gelatin

Coat
Hypromellose
Polysorbate 80
Purified talc special
Titanium dioxide

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

5 years.

6.4 Special precautions for storage

Do not store above 25ºC. Store in the original package.

6.5 Nature and contents of container

Aluminium and PVC blister packs containing 12 or 24 tablets.

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

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Trading as: Novartis Consumer Health

8 MARKETING AUTHORISATION NUMBER

PA 30/24/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 02 March 1988

Date of last renewal: 02 March 2003

10 DATE OF REVISION OF THE TEXT

March 2003