Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Aknemin 100

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Minocycline base 100 mg (as the hydrochloride Ph. Eur.) per capsule.

3 PHARMACEUTICAL FORM

Capsule, hard.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Minocycline is an antibiotic with a spectrum of activity similar to other tetracyclines but more active against *Staphylococcus aureus* and *Nocardia spp.*

It is indicated for the treatment of diseases associated with organisms sensitive to tetracyclines such as acne, respiratory infections. gonorrhoea, nocardiosis, staphylococcal infections; the chemoprophylaxis of meningococcal infections.

4.2 Posology and method of administration

For oral administration

Adults

1. Routine antibiotic use: 200 mg daily in divided doses.
2. Acne: 100 mg once daily
3. Gonorrhoea: In adult males, 200 mg initially followed by 100 mg every l2 hours for a minimum of 4 days with post-therapy cultures within 2-3 days. Adult females may require more prolonged therapy.
4. Prophylaxis of meningococcal infections: 100 mg twice daily for 5 days, usually followed by a course of rifampicin.

Children
Aknemin 100 is not recommended for children under 12 years old. For children above 12 years old the recommended dose is 50 mg every 12 hours.

The Elderly
Aknemin 100 may be used at the normal recommended dosage in elderly patients but caution is advised in patients with renal impairment.

The treatment of acne should be continued for a minimum of 6 weeks.

4.3 Contraindications

Hypersensitivity to tetracyclines, systemic lupus erythematosus, complete renal failure, children under 12 years old, pregnancy, lactation.

4.4 Special warnings and precautions for use

Aknemin 100 should be used with caution in patients with hepatic dysfunction and in conjunction with alcohol and other hepatotoxic drugs, and in patients with severe renal impairment. In cases of severe renal insufficiency, reduction of dose and monitoring of renal function may be required.

Cross-resistance between tetracyclines may develop in micro-organisms and cross-sensitisation in patients. Aknemin 100 should be discontinued if there are signs or symptoms of overgrowth of resistant organisms, e.g. enteritis, glossitis, stomatitis, vaginitis. pruritus ani or staphylococcal enteritis.

Patients taking oral contraceptives should be warned that if diarrhoea or breakthrough bleeding occurs there is a possibility of contraceptive failure.

Caution should be exercised in patients with Myasthenia Gravis as tetracyclines can cause weak neuromuscular blockade.

4.5 Interaction with other medicinal products and other forms of interaction

Tetracyclines decrease plasma prothrombin activity; reduced doses of concomitant anticoagulants may therefore be required. Aknemin 100 should not be used with penicillins. The absorption of Aknemin 100 is impaired by concomitant administration of antacids, and preparations containing iron, calcium, aluminium, or magnesium.

4.6 Pregnancy and lactation

Aknemin 100 should not be used in pregnancy unless essential. Yellow-brown discolouration of the teeth and enamel hypoplasia can occur when drugs of the tetracycline group are administered after the first trimester of pregnancy.

Aknemin 100 should not be given to lactating women.

4.7 Effects on ability to drive and use machines

Patients should be warned of the hazards of driving or operating machinery until the effect of treatment is known *(See 4.8)*.

4.8 Undesirable effects

Headache, dizziness, vertigo, ataxia, and tinnitus may occur, These disturbances are reversible within 3 - 48 hours of discontinuing therapy and occur less frequently when a low dose is given. Gastrointestinal disturbances may occur. Dermatological reactions are rare but erythema multiforme, Stevens-Johnson syndrome, exfoliative dermatitis. and photosensitivity have been reported.

Hypersensitivity reactions can include urticaria, fever, arthralgia, angioneurotic oedema, anaphylaxis and anaphylactoid purpura. Rarely pericarditis and pulmonary infiltration have been reported.

Isolated cases of systemic lupus erythematosus (SLE) and exacerbation of pre-existing SLE have been reported.

As with other tetracyclines, bulging fontanelles in infants and benign intracranial hypertension in adults have been reported. Treatment should be stopped if evidence of raised intracranial pressure develops.

Haemolytic anaemia, thrombocytopenia. neutropenia and eosinophilia have been reported with tetracyclines. In common with other tetracyclines. transient increases in liver function test values and rarely, hepatitis have been reported. There have been isolated incidences of pancreatitis.

When given over long periods, tetracyclines have been reported to produce brownish-black microscopic discolouration

of thyroid tissue; no abnormalities of function are known to occur.

Hyperpigmentation of skin or discolouration of teeth and buccal mucosa has been reported occasional]y. These are generally reversible on cessation of therapy. There are isolated cases of discolouration of conjunctiva, lacrimal secretions. breast secretions and perspiration. *(See 4.6).*

4.9 Overdose

There is no specific antidote. Treatment is gastric lavage with appropriate supportive treatment.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Minocycline is an antibiotic with a spectrum of activity similar to other tetracyclines but is more active against *Staphylococcus aureus* and *Nocardia spp.*

5.2 Pharmacokinetic properties

Minocycline is almost completely absorbed after oral administration.

Absorption is not significantly affected by the presence of food or milk. Doses of 200 mg followed by 100 mg every 12 hours produce plasma concentrations of 1 to 4 mg per ml.

Plasma half life is 12 - 16 hours in patients with normal renal function but increased in renal impairment.

Minocycline is widely distributed in body fluids and tissue. It crosses the placenta and is excreted in breast milk.

5.3 Preclinical safety data

No relevant preclinical safety data have been generated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol
Erythrosine (E127)
Red iron oxide (E172)
Yellow iron oxide (E172)
Titanium dioxide (E171)
Gelatin

6.2 Incompatibilities

None stated.

6.3 Shelf Life

24 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

PVC/aluminium foil blister of 14 in a cardboard outer containing 56 or 112 capsules.

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

None stated.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 0557/002/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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