

SUMMARY OF PRODUCT C

1. NAME OF THE FINISHED PHARMACEUTICA

Generic Name: Sildenafil Tablets USP Brand name: Penegra 100 mg F.C. Tablet

Strength: Sildenafil 100 mg/Tablet (as Sildenafil Citrat

Dosage form: Tablet (Film Coated)

Distribution category of the Product: Prescription Only

2. QUALITATIVE AND QUANTITATIVE COMPO

Each film coated tablet contains 140.8451 mg Silder

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet (Film Coated)

Smooth, well formed, diamond shaped blue colored side and bisect on other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Penegra is indicated in adult men with erectile dysfi maintain a penile erection sufficient for satisfactory se effective, sexual stimulation is required.

4.2 Posology and method of administration

The usual dose is 50 mg once daily. It should be Depending on effectiveness & tolerance, the dose may dose of 100 mg or decreased to 25 mg. The maximu factors are associated with increased plasma levels of problem, severe renal impairment and concomita erythromycin. Since higher plasma levels may increas events, a starting dose of 25 mg should be considered time to work if it is taken with a heavy meal.