Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Tilade Aerosol 2 mg per metered dose Pressurised Inhalation, Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered dose contains 2 mg of nedocromil sodium.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Pressurised inhalation, suspension.

Yellow, mint flavoured suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the management of reversible obstructive airways disease such as bronchial asthma, asthmatic bronchitis, exercise-induced asthma, late onset asthma and bronchospasm from external causes.

4.2 Posology and method of administration

For respiratory use.

Adults (including the elderly) and children over 2 years of age: Initially two actuations (4mg of nedocromil sodium) four times daily. Once symptomatic control has been achieved, the usual maintenance dose is two actuations twice daily.
Tilade is intended for regular usage and should not be used for the relief of symptoms in an acute attack.

4.3 Contraindications

Tilade is contra-indicated in patients with known hypersensitvity to any of the constituents.

4.4 Special warnings and precautions for use

Tilade should not be used for the relief of an acute attack of bronchospasm.

4.5 Interaction with other medicinal products and other forms of interaction

Not known.

4.6 Pregnancy and lactation

Studies with nedocromil sodium in pregnant and lactating animals have failed to reveal a hazard. However as with all new medicines caution should be exercised especially during the first trimester of pregnancy.
On the basis of animal studies and its physicochemical properties it is considered that only negligible amounts of nedocromil sodium may pass into human breast milk. There is no information to suggest that the use of nedocromil sodium by nursing mothers has any undesirable effects on the baby.

4.7 Effects on ability to drive and use machines

Tilade has no known effect on the ability to drive or operate machinery.

4.8 Undesirable effects

The principle side effects reported, are headache and upper gastrointestinal tract symptoms (nausea, vomiting, dyspepsia and abdominal pain). These are usually mild and transient. Some patients have reported a distinctive taste. In common with other inhaled medications Tilade may produce cough or bronchospasm.

4.9 Overdose

Animal studies have not shown evidence of toxic effects of nedocromil sodium even at high dosage, nor have extended human studies revealed any safety hazard with the drug. Overdosage is unlikely, therefore, to cause problems. However, if overdosage is suspected, treatment should be suppportive and directed to the control of the relevant symptoms.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Tilade contains nedocromil sodium, a non-steroidal agent, which has anti-inflammatory properties when administered topically in the lung. *In-vivo*, *ex-vivo* and *in-vitro* studies have shown that nedocromil sodium has beneficial effects on cellular, humoral and neuronal mechanisms thought to be involved in the inflammation of bronchial asthma. In the treatment of bronchial asthma, nedocromil sodium reduces bronchospasm, cough and bronchial hyper-reactivity, and improves objective measurements of lung function.

5.2 Pharmacokinetic properties

After inhalation of nedocromil sodium (in common with other drugs inhaled using MDI) a small fraction (generally 10-20%) reaches the lungs, while a major portion of the dose is deposited in the mouth or oropharynx and swallowed. The oral absorption of nedocromil sodium from the gastrointestinal tract is low, being approximately 2 % of an orally administered dose. Hence, nedocromil sodium measured in plasma following inhalation is considered to represent mainly the drug absorbed by the airways. After inhalation, plasma concentrations of nedocromil sodium reach a maximum within one hour post-dosing and decline with a half-life of 1-2 hours.

Nedocromil sodium is moderately (up to 89 %) and reversibly bound to human plasma proteins, and is not metabolised in man or animals. In man nedocromil sodium is excreted unchanged in the urine (approximately 70%) and in faeces (approximately 30 %).

5.3 Preclinical safety data

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitan trioleate
Dentomint
Saccharin sodium
Cryofluorane (propellant 114)
Dichlorodifluoromethane (propellant 12)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Keep the inhaler in the outer carton.
The canister contains a pressurised liquid. Do not expose to temperatures higher then 50°C.
Do not pierce the canister.

6.5 Nature and contents of container

An aluminium can fitted with a metering valve which delivers either 56 or 112 actuations (each containing 2 mg of nedocromil sodium) after priming.

Tilade Aerosol: An aerosol canister and a plastic adaptor with a dustcap packaged in an outer box.
Pack sizes: 56, 2 x 56, 112, 112 x 2.

Tilade with Fisonair: An aerosol canister and a plastic adaptor with a dustcap and a holding chamber packaged in an outer carton.
Pack sizes: 56, 2 x 56, 112, 112 x 2.

Tilade with Syncroner: An aerosol canister with a spacer device and a dustcap and a holding chamber packaged in an outer carton.
Pack sizes: 56, 2 x 56, 112, 112 x 2.

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

The inhaler should be well shaken (at least 5 times). If the inhaler has not been used for more than 2 days or if it is being used for the first time, one actuation should be released into the air.
Children and patients with difficulty in co-ordinating may benefit from using a holding chamber, to assist inhalation of the medication. The standard mouthpiece, but not the SYNCRONER® spacer device, is suitable for use with large volume holding chambers such as FISONAIR®.

Detailed instructions for use are contained in the Patient Information Leaflet supplied with each pack.

7 MARKETING AUTHORISATION HOLDER

Sanofi-aventis Ireland Ltd
Citywest Business Campus
Dublin 24

8 MARKETING AUTHORISATION NUMBER

PA0540/130/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 December 1986
Date of last renewal: 19 December 2006

10 DATE OF REVISION OF THE TEXT

March 2007