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## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE MEDICINAL PRODUCT

**IXEL 50 mg, hard capsule**

**IXEL 25mg, hard capsule**

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

IXEL 50mg:

Milnacipran hydrochloride.....50.00 mg

Quantity equivalent to Milnacipran free base.....43.55 mg

IXEL 25mg:

Milnacipran hydrochloride.....25.00 mg

Quantity equivalent to Milnacipran free base.....21.77 mg

For one hard capsule

For excipients, see 6.1

### 3. PHARMACEUTICAL FORM

Hard capsule.

Pink cap and body, imprinted with "Ixel 25".

Pink cap and rust-coloured body, imprinted with « Ixel 50 ».

### 4. CLINICAL PARTICULARS

#### 4.1. Therapeutic Indications

Treatment of major depressive episodes in adults.

#### 4.2. Dosology and Method of Administration

##### Dosage and Method of Administration

Recommended dosage is 100 mg a day in two divided 50 mg doses, 1 capsule morning and evening preferably during meals.

In this case, use the 50 mg capsules.

In the elderly, dosage adjustment is not necessary as long as renal function is normal. (see Pharmacokinetic properties).

In patients with renal failure, dosage adjustment is necessary.

The recommended dosage is reduced to 50 or 25 mg depending on the degree of alteration of renal function (see Pharmacokinetic properties).

In this case, use 25 mg capsules.

The following dosage adjustment is recommended: