

# POLLENTYME TABLETS POLLENTYME S

**SCHEDULING STATUS:**

S2

**PROPRIETARY NAME AND DOSAGE FORM:**

Pollentyme tablets  
Pollentyme S (syrup)

**COMPOSITION:**

Each tablet contains 10 mg loratadine (micronised).  
Each 5 ml contains 5 mg loratadine (micronised), and 0,1 % m/v preservative (sodium benzoate);  
"contains sugar".

**PHARMACOLOGICAL CLASSIFICATION:**

A: 5.7.1 Antihistaminics.

**PHARMACOLOGICAL ACTION:**

Loratadine is a long-acting, tricyclic antihistamine with highly selective peripheral H<sub>1</sub>-receptor antagonistic activity and is devoid of significant anticholinergic action.

**Pharmacokinetics:**

Loratadine is rapidly absorbed from the gastrointestinal tract after oral administration, peak plasma concentrations being attained in one hour. Bioavailability is increased and time to peak plasma concentrations is delayed when administered with food.

Loratadine undergoes extensive metabolism. The major metabolite, descarboethoxyloratadine has potent histamine-H<sub>1</sub> blocking activity. Reported mean half-lives for loratadine and descarboethoxyloratadine are 8,4 and 28 hours respectively. Loratadine is about 98% bound to plasma proteins; descarboethoxyloratadine is less extensively bound.

Loratadine and its metabolites have been detected in breast milk, but do not appear to cross the blood brain barrier to a significant extent.

Loratadine and its metabolites are excreted in the urine and faeces.

**INDICATIONS:**

Pollentyme is indicated for the relief of symptoms associated with allergic reactions including seasonal allergic rhinitis and chronic urticaria.

**CONTRA-INDICATIONS:**

Hypersensitivity to any of the ingredients. Cross-sensitivity to other antihistamines.

Impaired hepatic function.

Safety of Pollentyme in the elderly has not been established.

**WARNINGS:**

Elderly patients are especially susceptible to dizziness, sedation, confusion, hypotension and anticholinergic effects such as dry mouth and urinary retention.

Long term use of antihistamines may decrease salivary flow and contribute to development of caries, periodontal disease, oral candidiasis and discomfort.

Patients should avoid alcoholic drinks.

**INTERACTIONS:**

All sedatives and alcohol potentiate the central nervous system depressant effects of the antihistamines.

Tricyclic antidepressants or maprotiline potentiate anticholinergic effects if taken with antihistamines.

Monoamine oxidase inhibitors will potentiate both the drowsiness effect and the anticholinergic effects if taken with antihistamines. Concurrent use is not recommended.

Anticholinergics or drugs with anticholinergic activity will be potentiated if used concurrently with antihistamines.

Positive skin tests may be suppressed by antihistamines; therefore treatment with antihistamines should be stopped several days before the test.

**PREGNANCY AND LACTATION:**

Safety in pregnancy has not been established.

Loratadine and its metabolites are distributed into breast milk; therefore its administration during lactation is not advised.

**DOSAGE AND DIRECTIONS FOR USE:**

**Pollentyme tablets:**

*Adults and children over the age of 12 years:* One tablet once a day.

**Pollentyme S:**

*Adults and children over the age of 12 years:* 10 ml (2 medicine measures) once a day;

*Children 2 to 12 years:*

Body weight less than 30 kg: 5 ml (1 medicine measure) once a day

Body weight more than 30 kg: 5 ml (1 medicine measure) twice a day.

**Renal Failure/Decreased Renal Function:**

In patients with renal failure or decreased renal function (creatinine clearance < 30 ml per minute), the initial dose should be 10 mg every other day.

**SIDE-EFFECTS AND SPECIAL PRECAUTIONS:**

Side-effects with antihistamines vary in incidence and severity with each patient as much as with each drug.

Pollentyme is classified as a non-sedating antihistamine having little or no antimuscarinic effect.

The most frequently reported side-effect is sedation varying from slight drowsiness to deep sleep, and includes lassitude, dizziness and incoordination. These sedative effects, when they occur, may diminish after a few days of treatment.

Other more frequent side-effects include headache, psychomotor impairment and antimuscarinic effects, such as dry mouth, thickened respiratory-tract secretions, blurred vision, urinary difficulty or retention, constipation, and increased gastric reflux.

Below are side-effects listed according to the Organ Class Classification System:

Gastrointestinal:

Less frequently other gastrointestinal side-effects include nausea, vomiting, diarrhoea, or epigastric pain.

Cardiovascular effects:

Less frequently palpitations, arrhythmias and hypotension have been reported.

Hypersensitivity:

Less frequently rash and hypersensitivity reactions have been reported and include bronchospasm, angioedema and anaphylaxis. Cross-sensitivity to related drugs may occur.

Blood Disorders:

Agranulocytosis, leukopenia, haemolytic anaemia, and thrombocytopenia have been reported very rarely.

Central Nervous System:

Adverse effects reported include convulsions, myalgia, paraesthesias, extrapyramidal effects, tremor, sleep disturbances, depression, confusion, and tinnitus.

Other: Other reported side-effects include sweating and hair loss.

Caution should be used when the following medical conditions exist: severe cardiovascular disorders and epilepsy.

**Special Precautions:**

Pollentyme lacks significant sedative effects. Patients should, however be warned that a small number of individuals may experience sedation. It is therefore advisable to determine individual response before driving or performing complicated tasks. This effect may be compounded by the simultaneous intake of alcohol or other central nervous system depressants.

Elderly patients are also more susceptible to many adverse effects of antihistamines, including antimuscarinic effects, sedation and hypotension.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

Symptoms include drowsiness or paradoxical excitement, ataxia, tremors, athetosis, hallucinations and convulsions. Fixed dilated pupils with a flushed face, sinus tachycardia, dyspnoea, urinary retention, dry mouth and fever. Terminally there may be deepening coma and cardiorespiratory collapse.

Central excitatory effects constitute the greatest danger, particularly in children who are more likely to exhibit central nervous system stimulation. Adults more frequently exhibit central nervous system depression and the aged are particularly prone to experience hypotension.

Treatment of overdose:

The stomach should be emptied by emesis or lavage. There is no specific antidote and treatment is symptomatic and supportive.

**IDENTIFICATION:**

**Pollentyme tablets:** White or almost white, round, flat tablet scored on one side.

**Pollentyme S:** Clear to yellowish syrup, free from any visible particulate matter, with a characteristic peach flavour and odour.

**PRESENTATION:**

**Pollentyme tablets:** Blister packs of 10 and 30 tablets.

**Pollentyme S:** Brown (amber) glass bottles of 100 ml and 150 ml.

**STORAGE INSTRUCTIONS:**

Store in a cool (below 25°C), dry place.

KEEP OUT OF REACH OF CHILDREN.

**REGISTRATION NUMBERS:**

**Pollentyme tablets:** 34/5.7.1/0507

**Pollentyme S:** 37/5.7.1/0547

**NAME AND BUSINESS ADDRESS OF APPLICANT:**

Pharma Dynamics (Pty) Ltd.

F02 Grapevine House

Steenberg Office Park

WESTLAKE

7945

**DATE OF PUBLICATION OF THIS PACKAGE INSERT:**

23 April 2004

# POLLENTYME TABLETTE POLLENTYME S

## SKEDULERINGSSTATUS:

S2

## HANDELSNAAM EN DOSEERVORM:

Pollentyme tablette  
Pollentyme S (stroop)

## SAMESTELLING:

Elke tablet bevat 10 mg loratadien (gemikroniseer)  
Elke 5 ml bevat 5 mg loratadien (gemikroniseer) en 0,1% m/v preserveermiddel (natriumbensoaat);  
"bevat suiker".

## FARMAKOLOGIESE KLASSIFIKASIE:

A: 5.7.1 Antihistaminika

## FARMAKOLOGIESE WERKING:

Loratadien is 'n langwerkende, trisikliese antihistamien met hoogs selektiewe perifere H<sub>1</sub>-reseptor-antagonistiese aktiwiteit, sonder beduidende anticholinergiese werking.

## Farmakokinetika:

Loratadien word vinnig na orale toediening uit die spysverteringskanaal geabsorbeer en piek-plasmakonsentrasies word binne een uur bereik. Biobeskikbaarheid word verhoog en die periode voor piek-plasmakonsentrasies bereik word, word verleng wanneer dit saam met voedsel toegedien word.

Loratadien ondergaan uitgebreide metabolisme. Die hoofmetaboliet, deskarboetoksiloratadien besit kragtige histamien-H<sub>1</sub>-blokkeringsaktiwiteit. Gemiddelde halfleeftyd vir loratadien en deskarboetoksiloratadien van 8,4 en 28 uur onderskeidelike is aangemeld. Ongeveer 98% van loratadien is gebonde aan plasmaproteïene; deskarboetoksiloratadien is minder ekstensief gebonde.

Loratadien en sy metaboliete is al in borsmelk opgespoor, maar dit beweeg blykbaar nie in beduidende hoeveelhede deur die bloed-breinskans nie.

Loratadien en sy metaboliete word in die urine en faeces uitgeskei.

## INDIKASIES:

Pollentyme word aangedui vir die verligting van simptome wat aan allergiese reaksies, insluitend seisoenale allergiese rinitis en chroniese urtikarie, gekoppel is.

## KONTRA-INDIKASIES:

Hipersensitiwiteit teenoor enige van die bestanddele. Kruis-sensitiwiteit teenoor ander antihistamie.

Ingekorte lewerfunksie.

Veiligheid van Pollentyme in bejaardes is nie vasgestel nie.

## WAARSKUWINGS:

Bejaarde pasiënte is veral vatbaar vir duiseligheid, sedering, verwarring, hipotensie en anticholinergiese uitwerkings, soos droë mond en urienretensie.

Langdurige gebruik van antihistamie mag speekselvloeï verminder en bydra tot die ontwikkeling van karies, peridontale siekte, orale candidiasie, en ongemaak.

Pasiënte behoort alkoholiese drankte te vermy.

## INTERAKSIES:

Alle sedatiewe en alkohol versterk die sentrale senustelsel-depressante uitwerkings van die antihistamie.

Trisikliese antidepressante of maprotiëne versterk anticholinergiese uitwerkings wanneer dit saam met antihistamiene geneem word.

Monoamienoksidasie-inhibeerders sal beide die kalmerende en die anticholinergiese uitwerkings versterk wanneer dit saam met antihistamiene geneem word. Gelyktydige gebruik word nie aanbeveel nie.

Anticholinergiese middels of geneesmiddels met anticholinergiese aktiwiteit sal versterk word indien dit saam met antihistamiene gebruik word.

Positiewe veltoetse mag deur antihistamiene onderdruk word; behandeling met antihistamiene moet dus etlike dae voor die toets gestaak word.

#### **SWANGERSKAP AND LAKTASIE:**

Veiligheid tydens swangerskap is nie vasgestel nie.

Loratadien en sy metaboliete word in borsmelk versprei, en toediening tydens laktasie word dus nie aanbeveel nie.

#### **DOSIS EN GEBRUIKSAANWYSINGS:**

##### **Pollentyme tablette:**

*Volwassenes en kinders ouer as 12 jaar:*

Een tablet een keer per dag.

##### **Pollentyme S:**

*Volwassenes en kinders ouer as 12 jaar:*

10 ml (2 medisynemate) een keer per dag;

*Kinders 2 tot 12 jaar:*

Liggaamsmassa minder as 30 kg: 5 ml (1 medisynemaat) een keer per dag

Liggaamsmassa meer as 30 kg: 5 ml (1 medisynemaat) twee keer per dag.

Nierversaking/Ingekorte Nierfunksie:

In pasiënte met nierversaking of ingekorte nierfunksie (kreatinienopruiming <30 ml per minuut), moet 'n aanvangsdosis van 10 mg elke tweede dag gebruik word.

#### **NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:**

Neuwe-effekte met antihistamiene varieer ten opsigte van voorkoms en erns met elke pasiënt, asook met elke geneesmiddel.

##### Sentrale Senusisteem:

Sedering, duiseligheid, moegheid, lusteloosheid, wankoordinerings, tremor, verwarring, versteurde visie, diplopie, tinnitus, euforie, senuagtigheid, prikkelende gevoel en swakheid in die hande, prikkelbaarheid, nagmerries, slaaploosheid, hallusinasie, stuipe.

##### Anticholinergiese Uitwerkings:

Droë mond en lugweë, verdikking van slym, hoes, verhoogde sweetafskeiding, urinêre retensie of frekwensie, disurie.

Hoofpyn, benoude bors, hartkloppings, tagikardie, hipotensie.

##### Gastro-intestinale Versteurings:

Verlies aan aptyt, naarheid, braking, epigastriese ongesteldheid en diarree.

Verlaging in tonus en beweeglikheid van die spysverteringskanaal, wat gastriese refluks en hardlyghheid veroorsaak.

##### Hipersensitiwiteitsreaksies:

Allergiese dermatitis, geneesmiddelkoors, fotosensitiserings.

##### Bloedsiektes:

Agranulositose, hemolitiese anemie, leukopenie, trombositopenie.

Omzigtheid moet gebruik word wanneer die volgende mediese toestande teenwoordig is: ernstige kardiovaskulêre siektes en epilepsie.



**Spesiale Voorsorgmaatreëls:**

Pollentyme besit geen beduidende sederende uitwerkings nie. Pasiënte moet egter gewaarsku word dat 'n klein getal individue sedering mag ondervind. Dit is dus raadsaam om individuele reaksies te bepaal alvorens 'n persoon bestuur of ingewikkelde take uitvoer. Hierdie uitwerking mag deur die gelyktydige inname van alkohol en ander sentrale senusisteem-depressante versterk word. Bejaarde pasiënte is ook meer vatbaar vir baie van die nadelige uitwerkings van antihistamiene, insluitend antimuskariëse uitwerkings, sedering, en hipotensie.

**BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:**

Simptome sluit slaperigheid of paradoksale opwinding, ataksie, tremor, atetose, hallusinasies en stuipe in. Starre, gedilateerde pupille met 'n blosende gesig, sinus tagikardie, dispnee, urinêre retensie, droë mond en koors. Terminaal mag koma verdiep en kardio-respiratoriese kollaps kan voorkom.

Die grootste gevaar word aan sentrale eksitasie uitwerkings gekoppel, veral in kinders, wat meer geneig is om sentrale senusisteemstimulasie te ondervind. Volwassenes ondervind meer dikwels sentrale senusisteemonderdrukking en bejaardes is veral geneig om hipotensie te ontwikkel.

Behandeling van oordosering:

Die maag moet met emese of spoeling geledig word. Geen spesifieke teenmiddel is beskikbaar nie, en behandeling is simptomatiese en ondersteunend.

**IDENTIFIKASIE:**

**Pollentyme tablette:** Wit tot naaswit, ronde, plat tablet wat op een kant gekeep is.

**Pollentyme S:** Helder tot geelagtig stroop, ontslae van enige sigbaar uitsoekdeeltjies, met 'n kenmerkende perske smaak en geur.

**AANBIEDING:**

**Pollentyme tablette:** Stolpverpakkings van 10 en 30 tablette.

**Pollentyme S:** Bruin (amber) glas bottles van 100 ml of 150 ml.

**BERGINGSINSTRUKSIES:**

Bewaar op 'n koel (benede 25°C), droë plek.

HOU BUITE BEREIK VAN KINDERS.

**REGISTRASIENOMMERS:**

**Pollentyme tablette:** 34/5.7.1/0507

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**DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:**

23 April 2004