

אוגוסט 2026

רופא/ה רוקח/ת נכבד/ה,
ברצוננו להודיעך על עדכון בעלון לרופא של התכשיר:

Clopixol Acuphase

חומר פעיל:

zuclopenthixol acetate 50 mg/ml

להלן עדכונים מהותיים בלבד בעלון לרופא (טקסט מסומן ירוק משמעותו עדכון, טקסט מסומן צהוב משמעותו החמרה טקסט עם קו חוצה משמעותו טקסט מחוק):

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Clopixol Acuphase

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of solution for injection contains 50 mg zuclopenthixol (as acetate). Zuclopenthixol acetate 50 mg/ml.

For the full list of excipients, see section 6.1.

[...]

4.4. Special warnings and precautions for use

Caution should be exercised in patients having: liver disease; cardiac disease, or arrhythmias; severe respiratory disease; renal failure; epilepsy (and conditions predisposing to epilepsy, e.g. alcohol withdrawal or brain damage); Parkinson's disease; narrow angle glaucoma; prostatic hypertrophy; hypothyroidism; hyperthyroidism; myasthenia gravis; phaeochromocytoma and patients who have shown hypersensitivity to thioxanthenes or other antipsychotics.

[...]

Treatment:

Discontinuation of the neuroleptic. Symptomatic treatment and use of general supportive measures. Dantrolene and bromocriptine may be helpful. Symptoms may persist for more than a week after oral neuroleptics are discontinued and somewhat longer when associated with the depot forms of the drugs.

Extrapyramidal reactions may occur, especially during the first few days after an injection and in the early phase of treatment. In most cases these side effects can be satisfactorily controlled by reduction of dosage and/or use of antiparkinsonian drugs.

The routine prophylactic use of antiparkinsonian drugs is not recommended.

Antiparkinsonian drugs do not alleviate tardive dyskinesia and may aggravate them.

Reduction in dosage or, if possible, discontinuation of zuclopenthixol therapy is



recommended. In persistent akathisia a benzodiazepine or propranolol may be useful.

Dysphagia can occur secondary to Extrapyramidal symptoms as well to Sialorrhea, Sedation and Neuroleptic malignant syndrome and may lead to life-threatening complications such as aspiration pneumonia and choking.

Like other neuroleptics, zuclopenthixol acetate should be used with caution in patients with organic brain syndrome, convulsions or advanced hepatic, renal or cardiovascular disease.

[...]

4.8. Undesirable effects

The majority of undesirable effects are dose dependent. The frequency and severity are most pronounced in the early phase of treatment and decline during continued treatment.

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Antiparkinsonian drugs do not alleviate tardive dyskinesia and may aggravate it. Reduction in dosage or, if possible, discontinuation of zuclopenthixol therapy is recommended. In persistent akathisia a benzodiazepine or propranolol may be useful.

Frequencies are taken from the literature and spontaneous reporting. Frequencies are defined as:

Very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10000 to <1/1000), very rare (<1/10000), or not known (can not be estimated from the available data).

MedDRA System organ class	Frequen cy	Adverse Reaction
Blood and lymphatic system disorders	Rare	Thrombocytopenia, neutropenia, leukopenia, agranulocytosis.
Immune system disorders	Rare	Hypersensitivity, anaphylactic reaction.
Endocrine disorders	Rare	Hyperprolactinaemia.
Metabolism and nutrition disorders	Common	Increased appetite, weight increased.
	Uncommon	Decreased appetite, weight decreased.
	Rare	Hyperglycaemia, glucose tolerance impaired, hyperlipidaemia.
Psychiatric disorders	Common	Insomnia, depression, anxiety, nervousness, abnormal dreams, agitation, libido decreased.
	Uncommon	Apathy, nightmare, libido increased, confusional state.



Nervous system disorders	Very common	Somnolence, akathisia, hyperkinesia, hypokinesia, extrapyramidal symptoms (see section 4.4).
	Common	Tremor, dystonia, hypertonia, dizziness, headache, paraesthesia, disturbance in attention, amnesia, gait abnormal.
	Uncommon to Rare	Tardive dyskinesia, hyperreflexia, dyskinesia, parkinsonism, syncope, ataxia, speech disorder, hypotonia, convulsion, migraine.
	Very rare	Neuroleptic malignant syndrome.
Eye disorders	Common	Accommodation disorder, vision abnormal.
	Uncommon	Oculogyration, mydriasis.
Ear and labyrinth disorders	Common	Vertigo.
	Uncommon	Hyperacusis, tinnitus.
Cardiac disorders	Common	Tachycardia, palpitations.
	Rare	Electrocardiogram QT prolonged.
Vascular disorders	Uncommon	Hypotension, hot flush.
	Very rare	Venous thromboembolism
Respiratory, thoracic and mediastinal disorders	Common	Nasal congestion, dyspnoea.
Gastrointestinal disorders	Very common	Dry mouth.
	Common	Salivary hypersecretion, constipation, vomiting, dyspepsia, diarrhoea.
	Uncommon	Abdominal pain, nausea, flatulence.
	Rare	Dysphagia* (see section 4.4).
Hepato-biliary disorders	Uncommon	Liver function test abnormal.
	Very rare	Cholestatic hepatitis, jaundice.
Skin and subcutaneous tissue disorders	Common	Hyperhidrosis, pruritus.
	Uncommon	Rash, photosensitivity reaction, pigmentation disorder, seborrhoea, dermatitis, purpura.
Musculoskeletal and connective tissue disorder	Common	Myalgia.
	Uncommon	Muscle rigidity, trismus, torticollis.
Renal and urinary disorders	Common	Micturition disorder, urinary retention, polyuria.
Pregnancy, puerperium and	Not known	Drug withdrawal syndrome neonatal (see 4.6)



perinatal conditions		
Reproductive system and breast disorders	Uncommon	Ejaculation failure, erectile dysfunction, female orgasmic disorder, vulvovaginal dryness.
	Rare	Gynaecomastia, galactorrhoea, amenorrhoea, priapism.
General disorders and administration site conditions	Common	Asthenia, fatigue, malaise, pain.
	Uncommon	Thirst, injection site reaction, hypothermia, pyrexia.

**Dysphagia can occur secondary to extrapyramidal symptoms as well to sialorrhea, sedation, and neuroleptic malignant syndrome and may lead to life-threatening complications such as aspiration pneumonia and choking.*

[...]

8.3 REGISTRATION HOLDER

Swixx Biopharma Ltd.,

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Tel-Aviv 4355511, Israel

[...]

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העלון לרופא ולצרכן נשלח למאגר התרופות שבאתר משרד הבריאות www.health.gov.il לצורך העלאתו לאתר וניתן לקבלם מודפסים על ידי פניה לבעל הרישום.

בברכה
חגי וגנר
רוקח ממונה

