SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Concerta 18 mg Extended-Release Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each extended-release tablet contains 18 mg of methylphenidate hydrochloride USP.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Extended-release tablet.

Yellow, capsule-shaped tablet imprinted with “alza 18”.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Concerta is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children 6 years of age and older, adolescents, and adults up to the age of 65.

4.2 Posology and method of administration

Treatment should be initiated by a specialist experienced in the diagnosis and management of ADHD.

Pretreatment screening

Prior to initiating treatment, patients should be assessed:

• for the presence of cardiac disease, including careful medical history, family history of sudden death or ventricular arrhythmia, and physical examination;

• for family history and clinical evidence of motor or verbal tics or Tourette’s syndrome.

Recommended dosage and administration

Concerta should be administered orally once daily in the morning, with or without food.

The tablet must be swallowed whole with liquids and must not be chewed, divided, or crushed.

Patients new to methylphenidate

Patient age	Recommended starting dose	Dose range
Children 6–12 years	18 mg once daily	18–54 mg/day
Adolescents 13–17 years	18 mg once daily	18–72 mg/day (not to exceed 2 mg/kg/day)
Adults 18–65 years	18 or 36 mg once daily	18–72 mg/day

Patients currently using methylphenidate

The recommended dose conversion from prior methylphenidate regimens is shown below. Clinical judgment should be used for other regimens.

Previous methylphenidate daily dose	Recommended Concerta starting dose
5 mg methylphenidate twice or three times daily	18 mg every morning
10 mg methylphenidate twice or three times daily	36 mg every morning
15 mg methylphenidate twice or three times daily	54 mg every morning
20 mg methylphenidate twice or three times daily	72 mg every morning

Dose titration

Doses may be increased in 18 mg increments at weekly intervals in patients who have not achieved an optimal response at a lower dose.

Daily doses above 54 mg in children and above 72 mg in adolescents have not been studied and are not recommended.

Daily doses above 72 mg in adults are not recommended.

A 27 mg dosage strength is available for dose adjustment between 18 mg and 36 mg.

Dose reduction and discontinuation

If paradoxical aggravation of symptoms or other adverse reactions occur, reduce the dose or discontinue treatment.

If improvement is not observed after appropriate dosage adjustment over one month, treatment should be discontinued.

4.3 Contraindications

• Hypersensitivity to methylphenidate or to any excipient.

• Use during treatment with monoamine oxidase inhibitors (MAOIs), or within 14 days following discontinuation of an MAOI, due to risk of hypertensive crisis.

4.4 Special warnings and precautions for use

Abuse, misuse, and addiction: Concerta has a high potential for abuse and misuse, which can lead to substance use disorder, including addiction. Misuse and abuse of CNS stimulants may result in overdose and death. Patients should be assessed before prescribing and monitored throughout treatment. Patients and caregivers should be counselled on secure storage and proper disposal.

Risks to patients with serious cardiac disease: Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmias, coronary artery disease, or other serious cardiac disease.

Increase in blood pressure and heart rate: Blood pressure and pulse should be monitored.

Psychiatric adverse reactions: Prior to initiating treatment, patients should be screened for risk factors for bipolar disorder or psychosis. New psychotic or manic symptoms may occur even in patients without prior history.

Seizures: Stimulants may lower the convulsive threshold. Treatment should be discontinued if seizures occur.

Priapism: Prolonged and painful erections have been reported and require urgent medical attention.

Peripheral vasculopathy, including Raynaud's phenomenon: Careful observation for digital changes is necessary. Further evaluation, including rheumatology referral, may be appropriate.

Long-term suppression of growth in pediatric patients: Height and weight should be closely monitored. Treatment interruption may be required if growth suppression occurs.

Potential for gastrointestinal obstruction: Because the tablet is non-deformable, it should not be used in patients with pre-existing severe gastrointestinal narrowing or dysphagia.

Hematologic monitoring: Periodic CBC, differential, and platelet counts are advised during prolonged therapy.

Acute angle-closure glaucoma: Patients at risk, such as those with significant hyperopia, should be evaluated by an ophthalmologist.

Increased intraocular pressure and glaucoma: Use only if benefit outweighs risk in patients with open-angle glaucoma or increased IOP, and monitor closely.

Motor and verbal tics, and worsening of Tourette's syndrome: Assess before initiation and monitor regularly during treatment.

4.5 Interaction with other medicinal products and other forms of interaction

Interacting agent/class	Nature of interaction / recommendation
MAO inhibitors	Contraindicated due to risk of hypertensive crisis.
Vasopressor agents	Use cautiously due to possible increases in blood pressure.
Coumarin anticoagulants, anticonvulsants, tricyclic antidepressants, SSRIs	Methylphenidate may inhibit metabolism; dosage adjustment and monitoring may be required.
Halogenated anesthetics	Avoid use on the day of surgery due to risk of sudden blood pressure and heart rate increase.
Risperidone	Changes in dose of either medicine may increase the risk of extrapyramidal symptoms; monitor carefully.

4.6 Fertility, pregnancy and lactation

Pregnancy

Use in pregnancy should be based on careful assessment of benefit and risk. Reference information categorizes the product historically under Pregnancy Category C.

Labour and delivery

There are no adequate data on the use of methylphenidate during labour and delivery.

Breast-feeding

Caution should be exercised if administered to nursing mothers.

Fertility

Animal data do not suggest clinically relevant impairment of fertility at therapeutic exposure levels.

4.7 Effects on ability to drive and use machines

Concerta may impair the ability to perform potentially hazardous activities requiring complete mental alertness. Patients should be cautioned accordingly if affected by CNS or visual adverse effects.

4.8 Undesirable effects

The most common adverse reaction in double-blind clinical trials in children and adolescents (>5%) was upper abdominal pain.

The most common adverse reactions in adult patients (>5%) were decreased appetite, headache, dry mouth, nausea, insomnia, anxiety, dizziness, weight decreased, irritability, and hyperhidrosis.

The most common adverse reactions associated with discontinuation (≥1%) from either pediatric or adult clinical trials were anxiety, irritability, insomnia, and blood pressure increased.

System organ class	Selected adverse reactions
Cardiac disorders	Angina pectoris, bradycardia, extrasystoles, supraventricular tachycardia, ventricular extrasystoles
Eye disorders	Diplopia, increased intraocular pressure, mydriasis, visual impairment
General disorders	Chest pain, chest discomfort, drug effect decreased, hyperpyrexia, therapeutic response decreased
Hepatobiliary disorders	Hepatocellular injury, acute hepatic failure
Immune system disorders	Angioedema, anaphylactic reactions, auricular swelling, bullous conditions, exfoliative conditions, urticaria, pruritus, rash, eruptions, exanthemas
Investigations	Blood alkaline phosphatase increased, bilirubin increased, hepatic enzymes increased, platelet count decreased, white blood cell count abnormal
Musculoskeletal disorders	Arthralgia, myalgia, muscle twitching, rhabdomyolysis
Nervous system disorders	Convulsion, grand mal convulsion, dyskinesia, serotonin syndrome (with serotonergic drugs), motor and verbal tics
Psychiatric disorders	Disorientation, auditory and visual hallucinations, mania, logorrhea, libido changes
Reproductive system disorders	Priapism

Skin disorders	Alopecia, erythema
Vascular disorders	Raynaud's phenomenon

Reporting of Adverse Drug Reactions
Healthcare professionals are asked to report any suspected adverse drug reactions via the Pharmacy and Poisons Board's; Pharmacovigilance-Electronic-Reporting-System (PvERS)https://pharmacyboardkenya.org

4.9 Overdose

Clinical effects of overdose may include:

• Cardiovascular effects including tachyarrhythmias, hypertension or hypotension, vasospasm, myocardial infarction, aortic dissection, and Takotsubo cardiomyopathy.

• CNS effects including psychomotor agitation, confusion, hallucinations, serotonin syndrome, seizures, cerebral vascular accidents, and coma.

• Life-threatening hyperthermia and rhabdomyolysis.

Management

Consider the possibility of multiple drug ingestion. Because methylphenidate has a large volume of distribution and is rapidly metabolized, dialysis is not useful. Supportive and symptomatic management is required.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Psychostimulants, agents used for ADHD, centrally acting sympathomimetics.

ATC code: N06BA04.

Mechanism of action

Methylphenidate hydrochloride is a central nervous system stimulant. The mode of therapeutic action in ADHD is not known. Methylphenidate is thought to block the reuptake of norepinephrine and dopamine into the presynaptic neuron and increase the release of these monoamines into the extraneuronal space.

Pharmacodynamics

Methylphenidate is a racemic mixture comprised of the d- and l-isomers. The d-isomer is more pharmacologically active than the l-isomer.

5.2 Pharmacokinetic properties

Parameter	Details
Absorption	Rapid initial increase with an initial maximum at about 1 hour, followed by gradual ascending concentrations over the next 5–9 hours, with mean Tmax between 6 and 10 hours.
Bioavailability	Relative bioavailability of once-daily Concerta and immediate-release methylphenidate three times daily in adults is comparable.
Pharmacokinetic comparison after single dose	Cmax 3.7 ± 1.0 ng/mL; Tmax 6.8 ± 1.8 h; AUCinf 41.8 ± 13.9 ng·h/mL; t½ 3.5 ± 0.4 h for Concerta 18 mg once daily.
Dose proportionality	Dose-proportional increases in exposure observed over the studied dose range. No significant accumulation observed.
Distribution	Plasma concentrations decline biexponentially; half-life approximately 3.5 hours in adults and adolescents.
Metabolism	Primarily metabolized by de-esterification to PPAA, which has little or no pharmacologic activity.
Excretion	About 90% of radioactivity recovered in urine; PPAA accounts for approximately 80% of dose.
Food effect	No relevant difference in pharmacokinetics or pharmacodynamics after a high-fat breakfast. No evidence of dose dumping with food.
Alcohol effect	No increased release of methylphenidate in the first hour at alcohol concentrations up to 40% in vitro for the 18 mg tablet.
Special populations	No meaningful gender difference observed; data insufficient for ethnic differences. Not studied in children <6 years. No experience in hepatic insufficiency; renal insufficiency expected to have little effect.

5.3 Preclinical safety data

Carcinogenesis, mutagenesis and impairment of fertility

In lifetime carcinogenicity studies in mice, methylphenidate increased hepatocellular adenomas and, in males only, hepatoblastomas at high doses. The relevance of these findings to humans is unknown.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

• Butylated hydroxytoluene

• Carnauba wax

• Cellulose acetate

• Hypromellose

• Lactose

• Phosphoric acid

• Poloxamer

• Polyethylene glycol

• Polyethylene oxides

• Povidone

• Propylene glycol

• Sodium chloride

• Stearic acid

• Succinic acid

• Synthetic iron oxides

• Titanium dioxide

• Triacetin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store at 25°C; excursions permitted to 15–30°C.

Protect from humidity.

6.5 Nature and contents of container

HDPE Bottle pack, 30 tablets per pack

6.6 Special precautions for disposal and other handling

Patients and caregivers should be advised on proper disposal of unused tablets.

Because of abuse and diversion risk, secure handling and storage are recommended.

7. MARKETING AUTHORISATION HOLDER

Janssen Pharmaceuticals, Inc

1125 Trenton-Harbourton Road, Titusville, NJ 08560

USA

8. MARKETING AUTHORISATION NUMBER(S)

H2016/CTD2473/273

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of Re-registration: 02/04/2026

10. DATE OF REVISION OF THE TEXT

02/04/2026