PROFESSIONAL INFORMATION

SCHEDULING STATUS S5

1. NAME OF THE MEDICINE

ATTEZE™ 10, 10 mg Hard capsules
ATTEZE™ 18, 18 mg Hard capsules
ATTEZE™ 25, 25 mg Hard capsules
ATTEZE™ 40, 40 mg Hard capsules
ATTEZE™ 60, 60 mg Hard capsules
ATTEZE™ 80, 80 mg Hard capsules

WARNING:
Atomoxetine (contained in ATTEZE) increased the risk of suicidal ideation in short-term studies in children or adolescents with Attention-Deficit/Hyperactivity Disorder (ADHD). Anyone considering the use of ATTEZE in a child or adolescent must balance this risk with the clinical need. Co-morbidities occurring with ADHD may be associated with an increase in the risk of suicidal ideation and/or behaviour. Patients who are started on therapy should be monitored closely for suicidality (suicidal thinking and behaviour), clinical worsening, or unusual changes in behaviour.
Families and caregivers should be advised of the need for close observation and communication with the prescriber. ATTEZE is approved for ADHD in paediatric and adult patients. ATTEZE is not approved for major depressive disorder.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard capsule contains atomoxetine hydrochloride equivalent to 10 mg, 18 mg, 25 mg, 40 mg, 60 mg or 80 mg atomoxetine.
Sugar free.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Hard capsules.
ATTEZE 10 is presented as a white powder in a hard gelatin capsule of size no. 3, opaque white cap printed with '10' and opaque white body imprinted with 'mg'.
ATTEZE 18 is presented as white powder in a hard gelatin capsule of size no. 3, opaque rich yellow cap printed with '18' and opaque white body imprinted with 'mg'.
ATTEZE 25 is presented as white powder in a hard gelatin capsule of size no. 3, opaque blue cap printed with '25' and opaque white body imprinted with 'mg'.
ATTEZE 40 is presented as white powder in a hard gelatin capsule of size no. 3, opaque blue cap printed with '40' and opaque blue body imprinted with 'mg'.
ATTEZE 60 is presented as white powder in a hard gelatin capsule of size no. 2, opaque blue cap printed with '60' and opaque rich yellow body imprinted with 'mg'.
ATTEZE 80 is presented as white powder in a hard gelatin capsule of size no. 2, opaque brown cap imprinted with '80' and opaque white body imprinted with 'mg'.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ATTEZE is indicated for the treatment of attention-deficit/hyperactivity disorder (ADHD) in children 6 years of age or older, adolescents and adults.

4.2 Posology and method of administration

Posology

Treatment must be initiated by or under the supervision of a medical practitioner with appropriate knowledge and experience of childhood and/or adolescent behavioural disorders (for example, paediatrician or child/adolescent psychiatrist) (see section 4.4).

The recommended initial dose and subsequent dosage escalations of ATTEZE should not be exceeded because of potential side effects (see section 4.8).

ATTEZE hard capsules are not intended to be opened. ATTEZE is an eye irritant. See section 6.6 and *Method of administration* for instructions on what to do if capsule content comes into contact with the eye.

Dosing of children 6 years and older and adolescents up to 70 kg body mass

ATTEZE should be initiated at a total daily dose of approximately 0.5 mg/kg. The initial dose should be maintained for a minimum of 7 days prior to upward dose titration according to clinical response and tolerability. The recommended maintenance dose is approximately 1.2 mg/kg/day (depending on the patient's weight and available dosage strengths of ATTEZE). No additional benefit has been demonstrated for doses higher than 1.2 mg/kg/day.

Dosing of children and adolescents over 70 kg body mass and adults

ATTEZE should be initiated at a total daily dose of 40 mg. The initial dose should be maintained for a minimum of 7 days prior to upward dose titration according to clinical response and tolerability. The recommended maintenance dose is 80 mg daily. No additional benefit has been demonstrated for doses higher than 80 mg daily. The maximum recommended total daily dose for adults is 80 mg.

ATTEZE may be discontinued without tapering the dose.

Long-term use

No fixed dose dose-response studies have been conducted in adults. The recommended daily dose of 80 mg reflects the optimal daily dose of 1.2 mg/kg/day demonstrated in children and adolescents.

Missing a dose

If patients miss a dose, they should take it as soon as possible; however, they should not take more than the prescribed daily amount of ATTEZE in any 24-hour period.

Special populations

Elderly populations
The use of atomoxetine in patients over 65 years of age has not been systematically evaluated.

Paediatric population under six years of age:
The safety and efficacy of atomoxetine in children under 6 years of age have not been established. Therefore, ATTEZE should not be used in children under 6 years of age (see section 4.4).

Hepatic and renal insufficiency
For those ATTEZE patients who have hepatic insufficiency or end-stage renal disease, cautious titration of ATTEZE to the desired clinical response is recommended. ATTEZE clearance may be reduced in patients with hepatic insufficiency. For patients with moderate hepatic insufficiency (Child-Pugh Class B), initial and target doses should be reduced to 50 % of the usual doses. For patients with severe hepatic insufficiency (Child-Pugh Class C), initial dose and target doses should be reduced to 25 % of usual dose (see section 5.2).

ATTEZE may exacerbate hypertension in patients with end-stage renal disease (see section 4.8).

Method of administration
For oral use.
ATTEZE hard capsules should not be opened (see section 6.6), but swallowed whole with water. It may be taken with or without food.

4.3 Contraindications

- Hypersensitivity to atomoxetine or to any of the excipients of ATTEZE.
- ATTEZE should not be used in patients with uncontrolled hypertension or impairment of liver function.
- Monoamine oxidase inhibitors: ATTEZE should not be taken in combination with monoamine oxidase inhibitors (MAOI), including linezolid. ATTEZE should not be taken within a minimum of 2 weeks after discontinuing therapy with MAOI. Treatment with MAOI should not be initiated within 2 weeks after discontinuing ATTEZE.
- Severe cardiovascular disorders: ATTEZE should not be used in patients with severe cardiovascular disorders whose condition would be expected to deteriorate if they experienced increases in blood pressure or in heart rate that could be clinically important (for example 15 to 20 mmHg in blood pressure or 20 beats per minute in heart rate) (see section 4.4 - *Cardiovascular effects*).
- Pheochromocytoma: ATTEZE should not be used in patients with pheochromocytoma or a history of pheochromocytoma (see section 4.4 - *Cardiovascular effects*).
- Narrow angle glaucoma: The use of atomoxetine was associated with an increased incidence of mydriasis; therefore the use of ATTEZE is not recommended in patients with narrow angle glaucoma.

4.4 Special warnings and precautions for use

Treatment must only be initiated by or under the supervision of a medical practitioner with appropriate knowledge and experience of childhood and adolescent behaviour disorders (e.g. a paediatrician or child/adolescent psychiatrist).

Suicide-related behaviour, hostility
Suicidal behaviour, suicidal ideation, hostility (predominantly aggression, oppositional behaviour and anger) and emotional lability were more frequently observed among patients treated with atomoxetine (as in ATTEZE), compared to those treated with placebo but the differences were not statistically significant. Patients beginning treatment for ADHD should be carefully monitored for the appearance or worsening of suicide-related behaviour, hostility and emotional lability. The possibility of serious psychiatric adverse effects cannot be excluded.
There is evidence that the risk of psychiatric adverse events is increased in children with a personal history of mood disorders, or who have a family history of mood disorders.

Sudden death and pre-existing cardiac abnormalities
Sudden death has been reported in patients with structural cardiac abnormalities who were taking atomoxetine at usual doses. Although some serious structural cardiac abnormalities alone carry an increased risk of sudden death, ATTEZE should only be used with caution in patients with known serious structural cardiac abnormalities, and in consultation with a cardiac specialist.

Cardiovascular effects
ATTEZE can significantly increase the heart rate and blood pressure. Most patients experience a modest increase in heart rate (mean < 10 bpm) and/or increase in blood pressure (mean < 5 mm Hg) (see section 4.8).
However, combined data from controlled and uncontrolled ADHD clinical trials show that approximately 8-12 % of children and adolescents, and 6-10 % of adults experience more pronounced changes in heart rate (20 beats per minute or greater) and blood pressure (15-20 mmHg or greater). Analysis of these clinical trial data showed that approximately 15-26 % of children and adolescents, and 27-32 % of adults experiencing such changes in blood pressure and heart rate during treatment with atomoxetine had sustained or progressive increases. Long-term sustained changes in blood pressure may potentially contribute to clinical consequences such as myocardial hypertrophy.

As a result of these findings, patients who are being considered for treatment with ATTEZE should have a careful history and physical exam to assess for the presence of cardiac disease and should receive further specialist cardiac evaluation if initial findings suggest such history or disease.
It is recommended that heart rate and blood pressure be measured and recorded before treatment is started and, during treatment, after each adjustment of dose and then at least every 6 months to detect possible clinically important increases. For paediatric patients the use of a centile chart is recommended. For adults, current reference guidelines for hypertension should be followed.

ATTEZE should not be used in patients with severe cardiovascular or cerebrovascular disorders (see section 4.3). Severe cardiovascular disorders may include severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening dysrhythmias and channelopathies (disorders caused by the dysfunction of ion channels). Severe cerebrovascular disorders may include cerebral aneurysm or stroke.

ATTEZE should be used with caution in patients whose underlying medical conditions could be worsened by increases in blood pressure and heart rate, such as patients with hypertension, tachycardia, or cardiovascular or cerebrovascular disease.
Patients who develop symptoms such as palpitations, exertional chest pain, unexplained syncope, dyspnoea or other symptoms suggestive of cardiac disease during treatment with ATTEZE should undergo a prompt specialist cardiac evaluation.

Cerebrovascular effects
Patients with additional risk factors for cerebrovascular conditions (such as a history of cardiovascular disease, concomitant medications that elevate blood pressure) should be assessed at every visit for neurological signs and symptoms after initiating treatment with ATTEZE.

Hepatic effects
Spontaneous reports of liver injury, manifested by elevated hepatic enzymes and bilirubin with jaundice, have been reported, in some cases associated with severe liver injury, including acute liver failure, have also been reported. ATTEZE should be discontinued in patients with jaundice or laboratory evidence of liver injury and it should not be restarted.

Psychotic or manic symptoms
Treatment-emergent psychotic or manic symptoms, e.g., hallucinations, delusional thinking, mania or agitation in patients without a prior history of psychotic illness or mania can be caused by ATTEZE at usual doses. If such symptoms occur, consideration should be given to a possible causal role of ATTEZE, and discontinuation of treatment should be considered. The possibility that ATTEZE will cause the exacerbation of pre-existing psychotic or manic symptoms cannot be excluded.

Aggressive behaviour, hostility or emotional lability
Hostility (predominantly aggression, oppositional behaviour and anger) was more frequently observed in clinical trials among children, adolescents and adults treated with atomoxetine (contained in ATTEZE) compared to those treated with placebo. Emotional lability was more frequently observed in clinical trials among children treated with atomoxetine compared to those treated with placebo. Patients should be closely monitored for the appearance or worsening of aggressive behaviour, hostility or emotional lability.

Possible allergic events
Allergic reactions, including anaphylactic reactions, rash, angioedema and urticaria have been reported in patients taking atomoxetine (as in ATTEZE) (see section 4.8).

Seizures
Seizures are a potential risk with atomoxetine. ATTEZE should be introduced with caution in patients with a history of seizure. Discontinuation of ATTEZE should be considered in any patient developing a seizure or if there is an increase in seizure frequency where no other cause is identified.

Growth and development
Weight gain and longitudinal growth should be monitored during treatment with ATTEZE. Reportedly, paediatric patients treated with atomoxetine in ADHD clinical trials had a mean initial decrease in weight and height gain. Subsequently, over the long-term period, patients recovered to the mean weight and height predicted by group baseline data.
The amount of available long-term data is limited. Therefore, patients requiring long-term therapy should be carefully monitored.

Effects on micturition
In adult ADHD controlled trials, the rates of urinary retention and urinary hesitation were increased among the patients given atomoxetine, compared with patients on placebo. A complaint of urinary retention or urinary hesitancy should be considered potentially related to ATTEZE.

Raynaud's phenomenon
ATTEZE should not be used in patients with Raynaud's phenomenon.

New-onset or worsening of co-morbid depression, anxiety and tics
ATTEZE has been used in patients with ADHD without deterioration of conditions of motor tics, Tourette syndrome (children), co-morbid major depressive disorder (adolescents) and anxiety disorders (adults and children).

There have less frequently been reports of anxiety, depression or depressed mood and tics (see section 4.8). Patients who are being treated for ADHD with ATTEZE should be monitored for the appearance or worsening of anxiety symptoms, depressed mood and depression or tics.

Special populations
Paediatric population under six years of age
ATTEZE should not be used in patients less than six years of age as efficacy and safety have not been established in this age group.

Elderly patients (65 years and older)
The safety and efficacy of ATTEZE in elderly persons have not been established.

4.5 Interaction with other medicines and other forms of interaction

Effects of other medicines on ATTEZE
MAOIs
Concomitant use of ATTEZE and MAOIs is contraindicated (see section 4.3).

CYP2D6 inhibitors (SSRIs (e.g. fluoxetine, paroxetine), quinidine, terbinafine)
In patients receiving these medicines, atomoxetine exposure may be 6-10 8-fold increased and $C_{ss\,max}$ 3 to 4 times higher, because it is metabolised by the CYP2D6 pathway. Slower titration and final lower dosage of ATTEZE may be necessary in patients who are already taking CYP2D6 inhibitors. If a CYP2D6 inhibitor is prescribed or discontinued after titration to the appropriate ATTEZE dose has occurred, the clinical response and tolerability should be re-evaluated for that patient, to determine if dose adjustment is needed.

Caution is advised when combining ATTEZE with potent inhibitors of cytochrome P450 enzymes other than CYP2D6 in patients who are poor CYP2D6 metabolisers, as the risk of clinically relevant increases in atomoxetine exposure *in vivo* is unknown.

Salbutamol (or other beta-adrenergic receptor agonists)
ATTEZE should be administered with caution to patients treated with high dose inhaled, nebulised or systemically administered salbutamol (or other beta2-agonists) because the action of salbutamol on the cardiovascular effects can be potentiated.

Attention should be paid to monitoring heart rate and blood pressure, and dose adjustments may be justified for either ATTEZE or salbutamol (or other beta2-agonists) in the event of significant increases in heart rate and blood pressure during co-administration of these medicines.

Tabulated list of adverse reactions - child and adolescent patients:

System Organ Class/ Frequency	Adverse reaction
Infections and infestations	
Frequent:	Sinusitis
Immune system disorders	
Less frequent:	Hypersensitivity reactions, anaphylactic reactions, angioedema
Metabolism and nutrition disorders	
Frequent:	Decreased appetite, anorexia
Psychiatric disorders	
Frequent:	irritability, mood swings, insomnia, agitation, anxiety, depression and depressed mood, tics (see section 4.4)
Less frequent:	Suicide-related events, anger, aggression, hostility, emotional liability, psychosis (including hallucinations) (see section 4.4)
Frequency unknown:	Suicidal ideation
Nervous system disorders	
Frequent:	Headache, somnolence, sedation, dizziness
Less frequent:	Syncope, tremor, migraine, dyskinesia, paraesthesia, seizure (see section 4.4 and 4.5)
Eye disorders	
Frequent:	Mydriasis
Less frequent:	Vision blurred, conjunctivitis
Cardiac disorders	
Less frequent:	Palpitations, sinus tachycardia, QT-interval prolongation (see section 4.4 and 4.5)
Vascular disorders	
Less frequent:	Raynaud's phenomenon
Frequency unknown:	Peripheral vascular instability
Respiratory, thoracic and mediastinal disorders	
Less frequent:	Dyspnoea (see section 4.4)
Gastrointestinal disorders	
Frequent:	Abdominal pain, stomach discomfort, abdominal discomfort, epigastric discomfort, vomiting, nausea, constipation, dyspepsia
Hepatobiliary disorders	
Less frequent:	Increased blood bilirubin, abnormal/increased liver function tests, jaundice, hepatitis, liver injury, acute hepatic failure (see section 4.4)
Skin and subcutaneous tissue disorders	
Frequent:	Dermatitis, pruritus, rash
Less frequent:	Hypersensitivity, allergic reactions
Renal and urinary disorders	
Less frequent:	Urinary hesitation, urinary retention
Reproductive system and breast disorders	
Less frequent:	Priapism, male genital pain
General disorders and administrative site conditions	
Frequent:	Fatigue, lethargy, chest pain (see section 4.4)
Less frequent:	Asthenia
Investigations	
Frequent:	Increased blood pressure, increased heart rate, decreased weight

CYP2D6 poor metabolisers
The following adverse events occurred in at least 2 % of child and adolescent CYP2D6 poor metabolisers (PM) patients and were statistically significantly more frequent in PM patients compared with CYP2D6 extensive metabolisers (EM) patients: weight decreased, constipation, insomnia, depression, tremor, middle insomnia, syncope, conjunctivitis, early morning awakening, generalised anxiety disorder. In addition, in trials lasting up to 10 weeks, weight loss was more pronounced in PM patients.

Tabulated list of adverse reactions - adult patients:

System Organ Class/ Frequency	Adverse reaction
Infections and infestations	
Frequent:	Sinusitis
Immune system disorders	
Less frequent:	Allergic reactions, anaphylactic reactions, angioedema
Metabolism and nutrition disorders	
Frequent:	Decreased appetite
Psychiatric disorders	
Frequent:	Insomnia, agitation, libido decreased, sleep disorders, depression and depressed mood, anxiety (see section 4.4), Suicide-related events, suicidal ideation, aggression, anger, irritability, emotional liability, restlessness, psychosis (including hallucinations) (see section 4.4)
Less frequent:	
Nervous system disorders	
Frequent:	Headache, dizziness, dysgeusia, paraesthesia, sedation, tremor
Less frequent:	Syncope, migraine, hypoaesthesia, seizures (see section 4.4 and 4.5)
Eye disorders	
Less frequent:	Vision blurred
Cardiac disorders	
Frequent:	Palpitations, tachycardia
Less frequent:	QT-interval prolongation, stroke, myocardial infarction, sudden death (see section 4.4 and 4.5)
Vascular disorders	
Frequent:	Flushing, hot flushes
Less frequent:	Raynaud's phenomenon, peripheral coldness
Frequency unknown:	Peripheral vascular instability
Respiratory, thoracic and mediastinal disorders	
Less frequent:	Dyspnoea (see section 4.4), rhinorrhoea
Gastrointestinal disorders	
Frequent:	Dry mouth, nausea, abdominal pain, abdominal discomfort, epigastric discomfort, vomiting, constipation, dyspepsia, flatulence
Hepatobiliary disorders	
Less frequent:	Increased blood bilirubin, abnormal/increased liver function tests, jaundice, hepatitis, liver injury, acute hepatic failure (see section 4.4)
Skin and subcutaneous tissue disorders	
Frequent:	Dermatitis, hyperhidrosis, rash
Less frequent:	Allergic reactions and angioneurotic oedema, urticaria, pruritus
Musculoskeletal and connective tissue disorders	
Less frequent:	Muscle spasms
Renal and urinary disorders	
Frequent:	Dysuria, pollakiuria, urinary hesitation, urinary retention
Less frequent:	Micturition urgency
Reproductive system and breast disorders	
Frequent:	Dysmenorrhoea, ejaculation disorders, erectile dysfunction, prostatitis, male genital pain
Less frequent:	Priapism, ejaculation failure, irregular menstruation, abnormal orgasm
General disorders and administrative site conditions	
Frequent:	Asthenia, fatigue, lethargy, chills, feeling jittery, irritability, thirst
Less frequent:	Feeling cold, chest pain (see section 4.4)
Investigations	
Frequent:	Increased blood pressure, increased heart rate, decreased weight

Summary of the safety profile
In adult ADHD clinical trials, the following system organ classes had the highest frequency of adverse events during treatment with atomoxetine: gastrointestinal, nervous system and psychiatric disorders. The most frequent adverse events reported were decreased appetite, insomnia, headache, dry mouth and nausea. The majority of these events were mild or moderate in severity and the events most frequently reported as severe were nausea, insomnia, fatigue and headache. A complaint of urinary retention or urinary hesitancy in adults should be considered potentially related to atomoxetine.
The following table of undesirable effects is based on adverse event reporting and laboratory investigations from clinical trials and post-marketing spontaneous reports in adults:

Management of overdose
An airway should be established. Monitoring of cardiac and vital signs is recommended, along with appropriate symptomatic and supportive measures. The patient should be observed for a minimum of 6 hours. Activated charcoal may be useful in limiting absorption if the patient presents within one hour of ingestion. Because ATTEZE is highly protein-bound, dialysis is not likely to be useful in the treatment of overdose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 1.2 Psychoanaleptics
Pharmacotherapeutic group: Psychoanaleptics, centrally acting sympathomimetics, ATC code: N06BA09

Mechanism of action
Atomoxetine is a selective inhibitor of the pre-synaptic norepinephrine (noradrenaline) transporter, without directly affecting the serotonin or dopamine transporters. Atomoxetine has minimal affinity for other noradrenergic receptors, or for other neurotransmitter transporters or receptors.

5.2 Pharmacokinetic properties

The pharmacokinetics of atomoxetine in children and adolescents are similar to those in adults. The pharmacokinetics of atomoxetine have not been evaluated in children under six years of age.

Absorption
Atomoxetine is well absorbed after oral administration. The mean maximal observed plasma concentration (C_{max}) is reached within 1 to 2 hours after dosing. Atomoxetine can be taken with or without food.

Distribution
Atomoxetine is widely distributed and is extensively bound to plasma proteins, primarily albumin.

Biotransformation
Atomoxetine is mainly metabolised through the cytochrome P450 2D6 (CYP2D6) enzymatic pathway.
Caucasian populations who have higher plasma concentrations of atomoxetine compared with individuals with reduced activity of this pathway (poor metabolisers). For poor metabolisers, AUC of atomoxetine is approximately 10-fold greater and $C_{ss\,max}$ is about 5-fold greater than extensive metabolisers.
The major oxidative metabolite formed is 4-hydroxyatomoxetine, that is glucuronidated 4-Hydroxyatomoxetine is equipotent to atomoxetine but circulates in plasma at much lower concentrations. Although 4-hydroxyatomoxetine is primarily formed by CYP2D6 in individuals that lack CYP2D6 activity, 4-hydroxyatomoxetine can be formed by several other cytochrome P450 enzymes, but at a slower rate. Atomoxetine does not inhibit or induce the CYP2D6 pathway.

Other Cytochrome P450 Enzymes: Atomoxetine did not cause clinically significant inhibition or induction of other cytochrome P450 enzymes, including CYP1A2, CYP3A, and CYP2C9.

Elimination
The mean elimination half-life of atomoxetine after oral administration is 3.6 hours in extensive metabolisers and 21 hours in poor metabolisers. Atomoxetine is excreted mainly in the urine, primarily as 4-hydroxyatomoxetine-*O*-glucuronide.

Linearity/non-linearity
Pharmacokinetics of atomoxetine is linear over the range of doses studied in both extensive and poor metabolisers.

Special populations
Hepatic impairment
Hepatic impairment results in a reduced atomoxetine clearance, increased atomoxetine exposure (AUC can increase 2-fold in moderate impairment and 4-fold in severe impairment) and a prolonged half-life of the parent substance.
In patients with moderate to severe hepatic impairment (Child Pugh Class B and C) initial and target doses should be adjusted (see section 4.2).

Renal impairment
Atomoxetine mean plasma concentrations for end-stage renal disease patients are generally higher than the mean for healthy persons. After adjustment for body weight, the differences between the two groups may be minimised and dose adjustment may not be required. See section 4.2.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsules content
Pregelatinized maize starch (Starch 1500)
Silica, colloidal anhydrous
Dimeticone (350)

Capsule shell

ATTEZE 10 mg hard capsules
Gelatin
Sodium lauryl sulphate (E487)
Titanium dioxide (E171)
Indigo carmine (E132)

ATTEZE 18 mg hard capsules
Gelatin
Sodium lauryl sulphate (E487)
Titanium dioxide (E171)
Iron oxide yellow (E172)

ATTEZE 25 mg hard capsules
Gelatin
Sodium lauryl sulphate (E487)
Titanium dioxide (E171)
Indigo carmine (E132)

ATTEZE 40 mg hard capsules
Gelatin
Sodium lauryl sulphate (E487)
Titanium dioxide (E171)
Indigo carmine (E132)

ATTEZE 60 mg hard capsules
Gelatin
Sodium lauryl sulphate (E487)
Titanium dioxide (E171)
Indigo carmine (E132)
Iron oxide yellow (E172)

ATTEZE 80 mg hard capsules
Gelatin
Sodium lauryl sulphate (E487)
Titanium dioxide (E171)
Iron oxide red (E172)
Iron oxide yellow (E172)
Printing ink (black)
Shellac (Glaze-45 % (20 % esterified) in ethanol
Iron oxide black (E172)
Propylene glycol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at or below 25 °C, in the original packaging. Keep blisters in the carton until required for use.

6.5 Nature and contents of container

A cardboard box containing transparent PVC/PE/PCTFE-aluminium foil blisters or PA/Al/PVC-aluminium foil blisters.
Packs of 7, 14, 28 or 30 hard capsules.
Not all pack sizes are necessarily marketed at any one time.

6.6 Special precautions for disposal and other handling

The capsules are not intended to be opened. Atomoxetine is an ocular irritant. In the event of the capsules content coming in contact with the eye, the affected eye should be flushed immediately with water, and medical advice obtained. Hands and any potentially contaminated surfaces should be washed as soon as possible.

7. HOLDER OF REGISTRATION CERTIFICATES

Adcock Ingram Limited
1 New Road,
Erand Gardens,
Midrand, 1685,
Customer Care: 0860 ADCOCK / 232625

8. REGISTRATION NUMBER (S)

ATTEZE 10: S1/1.2/1044
ATTEZE 18: S1/1.2/1045
ATTEZE 25: S1/1.2/1046
ATTEZE 40: S1/1.2/1047
ATTEZE 60: S1/1.2/1048
ATTEZE 80: S1/1.2/1049

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09 February 2021

10. DATE OF REVISION OF THE TEXT

14 April 2022