XEPLION® 50 mg, 75 mg, 100 mg & 150 mg prolonged release suspension for injection PRESCRIBING INFORMATION

ACTIVE INGREDIENT(S): 50 mg, 75 mg, 100 mg or 150 mg paliperidone.

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

INDICATION(S): XEPLION is indicated for maintenance treatment of schizophrenia in adult patients stabilised with paliperidone or risperidone. In selected adult patients with schizophrenia and previous responsiveness to oral paliperidone or risperidone, XEPLION may be used without prior stabilisation with oral treatment if psychotic symptoms are mild to moderate and a long-acting injectable treatment is needed.

DOSAGE & ADMINISTRATION: Intramuscular use only. Initiation doses (days 1 and 8) must be administered in deltoid muscle for therapeutic concentrations to be rapidly attained. **Adults:** 150 mg on treatment day 1 and 100 mg one week later (day 8 ± 4), both doses administered in deltoid muscle, using 1½ inch, 22 gauge needle (38.1 mm x 0.72 mm) for patients □ 90 kg, or 1-inch, 23 gauge needle (25.4 mm x 0.64 mm) for those < 90 kg. The third dose should be administered one month after the second initiation dose. Recommended monthly maintenance dose is 75 mg (range 50 mg-150 mg) in either deltoid or gluteal muscle. Recommended needle size for maintenance administration of XEPLION into deltoid muscle is as for initiation doses, and for the gluteal muscle is the 1½-inch, 22 gauge needle (38.1 mm x 0.72 mm). To avoid a missed monthly maintenance dose patients may be given injection up to 7 days before or after the monthly time point. Consider maintenance doses in upper range for overweight/obese patients. Adjust maintenance dose at monthly intervals as necessary. Alternate injections between left and right sides. Discontinue previous oral paliperidone or risperidone at time of initiation of XEPLION treatment (gradual withdrawal may benefit some patients). When switching patients from RISPERDAL® CONSTA™, initiate XEPLION in place of next scheduled injection, continue at monthly intervals. **Children:** No safety or efficacy data available. **Elderly:** No safety or efficacy data available for patients > 65 years. **Renal impairment:** ***Mild*** (creatinine clearance ≥ 50 to < 80 ml/min): Initiate with 100 mg on treatment day 1 and 75 mg one week later (day 8). Recommended monthly maintenance dose 50 mg. ***Moderate or severe*** (creatinine clearance < 50 ml/min): Not recommended. **Hepatic impairment:** Caution in severe hepatic impairment.

CONTRAINDICATIONS: Hypersensitivity to paliperidone, risperidone or any of the excipients.

SPECIAL WARNINGS & PRECAUTIONS: Do not use in acutely agitated or severely psychotic patients. Caution in cardiovascular disease (including family history of QT prolongation), cerebrovascular disease (especially elderly patients with dementia and risk factors for stroke), hypotension/ hypotensive states, prolactin-dependent tumours, seizures (or conditions that lower seizure threshold), Parkinson's disease and dementia with Lewy bodies. Discontinue all antipsychotics if neuroleptic malignant syndrome occurs. Consider discontinuation of all antipsychotics if tardive dyskinesia occurs. Caution is warranted in patients receiving both, psychostimulants (e.g., methylphenidate) and paliperidone concomitantly, as extrapyramidal symptoms could

emerge when adjusting one or both medications. Gradual withdrawal of stimulant treatment is recommended. Monitoring of white cell count (WCC) may be required. Discontinue XEPLION at first sign of clinically significant WCC in absence of other causes or if severe neutropenia (absolute neutrophil count <1 X 10^9/L). Rarely, anaphylactic reactions reported in patients previously tolerating oral risperidone/paliperidone. If occur, discontinue XEPLION, initiate general supportive measures and monitor until resolved. Appropriate clinical monitoring advised in patient with or at risk of diabetes. Advise of potential for weight gain, monitor weight regularly. Advise male patients to seek urgent medical care if priapism not resolved within 4 hours. Appropriate care advised for patients who will experience conditions that elevate core body temperature. Identify all possible risk factors for venous thromboembolism (VTE) before and during treatment and take preventive measures. Antiemetic effect (observed in paliperidone preclinical studies) may mask other conditions including overdose with certain medicines. Avoid inadvertent injection into a blood vessel. Intraoperative floppy iris syndrome (IFIS) has been observed during cataract surgery in patients treated with medicines with alpha1a-adrenergic antagonist effect, such as XEPLION.

SIDE EFFECTS: Very common: insomnia. **Common:** upper respiratory tract infection, urinary tract infection, influenza, hyperprolactinaemia, hyperglycaemia, weight increased, weight decreased, decreased appetite, agitation, depression, anxiety, parkinsonism, akathisia, sedation/somnolence, dystonia, dizziness, dyskinesia, tremor, headache, tachycardia, hypertension, cough, nasal congestion, abdominal pain, vomiting, nausea, constipation, diarrhoea, dyspepsia, toothache, transaminases increased, musculoskeletal pain, back pain, arthralgia, amenorrhoea, pyrexia, asthenia, fatigue and injection site reaction. **Other side effects reported with paliperidone include:** pneumonia, respiratory tract infection, cellulitis, subcutaneous abscess, thrombocytopenia, head titubation neutropenia, agranulocytosis, hypersensitivity, anaphylactic reaction, inappropriate antidiuretic hormone secretion, diabetic ketoacidosis, diabetes mellitus, hypoglycaemia, water intoxication, neuroleptic malignant syndrome, tardive dyskinesia, cerebral ischaemia, loss of consciousness, convulsion, diabetic coma, glaucoma, atrial fibrillation, atrioventricular block, bradycardia, pulmonary embolism, venous thrombosis, pulmonary congestion, pneumonia aspiration, pancreatitis, faecaloma, intestinal obstruction, ileus, jaundice, Stevens-Johnson syndrome/toxic epidermal necrolysis, angioedema, rhabdomyolysis, urinary retention, hypothermia, body temperature increased, drug withdrawal syndrome (including neonatal), injection site necrosis, respiratory tract congestion, wheezing, seborrhoeic dermatitis, galactorrhoea, priapism, . ***Injection site reactions:*** mild to moderate pain most commonly reported (tended to lessen in frequency and intensity over time). ***Weight gain:*** 12 % of XEPLION-treated subjects experienced weight gain of 7% (from double-blind phase to endpoint) during 33-week open-label phase of long-term recurrence prevention study. ***Laboratory tests: Serum prolactin:*** increases in serum prolactin observed in clinical trial subjects (both genders) with XEPLION. Adverse reactions suggesting increase in prolactin levels reported overall in <1% of subjects. ***Class effects:*** Ventricular arrhythmias, sudden unexplained death, cardiac arrest, and Torsade de pointes may occur with antipsychotics. Cases of venous thromboembolism, including pulmonary embolism and deep vein thrombosis, also reported.

Refer to SmPC for other side effects.

PREGNANCY: Should not be used during pregnancy unless clearly necessary.

LACTATION: Should not be used while breast-feeding.

INTERACTIONS: Caution with medicines that prolong QT interval e.g., class IA and class III antiarrhythmics, some antihistaminics, some other antipsychotics, some antimalarials. ***Potential for XEPLION to affect other medicines:*** Caution in conjunction with: other centrally acting medicines e.g., anxiolytics, antipsychotics, hypnotics, opiates, alcohol; medicines known to lower seizure threshold i.e., phenothiazines, butyrophenones, clozapine, tricyclics, SSRIs, tramadol, mefloquine etc; medicines capable of inducing orthostatic hypotension (an additive effect may be observed when XEPLION is co-administered); levodopa and other dopamine agonists (paliperidone may antagonize their effect- use lowest effective dose of each treatment if this combination necessary e.g., end-stage Parkinson's disease). Interaction of XEPLION with lithium unlikely. ***Potential for other medicines to affect XEPLION:*** Concomitant administration of oral paliperidone and paroxetine (a potent CYP2D6 inhibitor) showed no clinically significant effect on paliperidone pharmacokinetics. Coadministration of oral paliperidone once daily with carbamazepine 200 mg twice daily decreases plasma concentration of paliperidone by 37%. Re-evaluate/increase XEPLION dose at carbamazepine initiation. No clinically significant interaction expected between valproate and XEPLION. Caution when XEPLION is co-administered with risperidone or with oral paliperidone for extended periods of time. Limited safety data for concomitant use of XEPLION with other antipsychotics. The combined use of psychostimulants (e.g. methylphenidate) with paliperidone can lead to extrapyramidal symptoms upon change of either/both treatments.

Refer to SmPC for full details of interactions.

LEGAL CATEGORY: Prescription Only Medicine.

PRESENTATIONS, PACK SIZES, MARKETING AUTHORISATION NUMBERS & BASIC NHS COSTS:

PRESENTATION	PACK SIZE	MARKETING AUTHORISATION NUMBER	BASIC NHS COST
50 mg pre-filled syringe	1 dose	PLGB 00242/0708	£183.92
		EU/1/11/672/002	
75 mg pre-filled syringe		PLGB 00242/0709	£244.90
		EU/1/11/672/003	
100 mg pre-filled syringe		PLGB 00242/0710	£314.07
		EU/1/11/672/004	
150 mg pre-filled syringe		PLGB 00242/0711	£392.59
		EU/1/11/672/005	

MARKETING AUTHORISATION HOLDER:

Great-Britain (PLGB): Janssen-Cilag Limited, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG UK.

Northern Ireland (EU); Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Belgium.

FURTHER INFORMATION IS AVAILABLE FROM: Janssen-Cilag Limited, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire HP12 4EG UK.

Prescribing information last revised: August 2023.

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Janssen-Cilag Limited on 01494 567447 or at dsafety@its.jnj.com.

Trevicta® 175 mg, 263 mg, 350 mg & 525 mg prolonged release suspension for injection PRESCRIBING INFORMATION

ACTIVE INGREDIENT(S): 175 mg, 263 mg, 350 mg & 525 mg paliperidone.

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

INDICATION(S): TREVICTA, a 3-monthly injection, is indicated for the maintenance treatment of schizophrenia in adult patients who are clinically stable on 1-monthly paliperidone palmitate injectable product.

DOSAGE & ADMINISTRATION: Intramuscular injection. Patients who are treated with 1-monthly paliperidone palmitate injectable (4 months or more) and do not require dose adjustment may be switched to TREVICTA. **Adults:** Administer dose in either deltoid or gluteal muscle. Deltoid administration, use 1½ inch, 22 gauge needle

(0.72 mm x 38.1 mm) patients ≥ 90 kg, or 1-inch, 22 gauge needle (0.72 mm x 25.4 mm) patients < 90 kg. For gluteal administration use the 1½-inch, 22 gauge needle (0.72 mm x 38.1 mm). Initiate TREVICTA in place of the next scheduled dose of 1-month paliperidone palmitate injectable (± 7 days). Base TREVICTA dose on the previous 1-month paliperidone palmitate injectable dose using a 3.5-fold higher dose. Thereafter TREVICTA should be administered by intramuscular injection once every 3 months (± 2 weeks). Dose adjustment of TREVICTA can be made every 3 months in increments within the range of 175 mg to 525 mg. Alternate injections between left and right sides. **Children:** No safety or efficacy data available. **Elderly:** No safety or efficacy data available for patients
> 65 years. **Renal impairment:** ***Mild*** (creatinine clearance ≥ 50 to < 80 ml/min): dose should be adjusted. Stabilise patient using 1-month paliperidone palmitate injectable, and then transition to TREVICTA. ***Moderate or severe*** (creatinine clearance < 50 ml/min): Not recommended.
Hepatic impairment: Caution in severe hepatic impairment.

CONTRAINDICATIONS: Hypersensitivity to paliperidone, risperidone or any of the excipients.

SPECIAL WARNINGS & PRECAUTIONS: Do not use in acutely agitated or severely psychotic patients. Not recommended in elderly dementia patients. Caution in cardiovascular disease (including family history of QT prolongation), cerebrovascular disease, hypotension, prolactin-dependent tumours, seizures, Parkinson's disease and in conjunction with medicines that prolong QT interval. May induce orthostatic hypotension. If tardive dyskinesia occurs, consider discontinuing all antipsychotics. Caution is warranted in patients receiving both, psychostimulants (e.g., methylphenidate) and paliperidone concomitantly, as extrapyramidal symptoms could emerge when adjusting one or both medications. Gradual withdrawal of stimulant treatment is recommended. Events of leucopenia, neutropenia, and agranulocytosis reported with antipsychotics, including TREVICTA, additional monitoring or cessation of treatment may be required. If Neuroleptic Malignant Syndrome (NMS) occurs discontinue all antipsychotics. Rarely, anaphylactic reactions reported in patients previously tolerating oral risperidone/paliperidone. If occur, discontinue TREVICTA, initiate general supportive measures, monitor until resolved. Appropriate clinical monitoring in diabetics and those with risk factors for diabetes advisable. Advise of potential for weight gain, monitor weight regularly. Priapism reported with oral

paliperidone. Caution in patients experiencing conditions which may contribute to core body temperature elevation. Identify all possible risk factors for venous thromboembolism (VTE) before and during treatment and take preventive measures. Antiemetic effect (observed in paliperidone preclinical studies) may mask overdosage with certain medicines, intestinal obstruction, Reye's syndrome, brain tumour etc. Avoid inadvertent injection into a blood vessel. Intraoperative floppy iris syndrome (IFIS) observed during cataract surgery in patients treated with medicines with alpha1a-adrenergic antagonist effect, such as TREVICTA.

SIDE EFFECTS: Very common: insomnia. **Common:** upper respiratory tract infection, urinary tract infection, influenza, hyperprolactinaemia, hyperglycaemia, weight increased, weight decreased, decreased appetite, agitation, depression, anxiety, parkinsonism, akathisia, sedation/ somnolence, dystonia, dizziness, dyskinesia, tremor, headache, tachycardia, hypertension, cough, nasal congestion, abdominal pain, vomiting, nausea, constipation, diarrhoea, dyspepsia, toothache, transaminases increased, musculoskeletal pain, back pain, arthralgia, amenorrhoea, pyrexia, asthenia, fatigue, injection site reaction. **Other side effects reported with paliperidone include:** pneumonia, respiratory tract infection, cellulitis, thrombocytopenia, diabetes mellitus, electrocardiogram QT prolonged, bradycardia, subcutaneous abscess, neutropenia, inappropriate antidiuretic hormone secretion, diabetic ketoacidosis, NMS, cerebral ischaemia, unresponsive to stimuli, loss of consciousness, depressed level of consciousness, glaucoma, atrial fibrillation, pulmonary congestion, pancreatitis, faecaloma, urinary retention, hypothermia, agranulocytosis, anaphylactic reaction, water intoxication, diabetic coma, pulmonary embolism, pneumonia aspiration, intestinal obstruction, seborrhoeic dermatitis, galactorrhoea, ileus, Stevens-Johnson syndrome/toxic epidermal necrolysis, angioedema, rhabdomyolysis, injection site necrosis, priapism, respiratory tract congestion, wheezing, head titubation, thrombocytopenia. **Other side effects reported with risperidone (paliperidone is the active metabolite of risperidone):** ***Weight gain:*** 10% of TREVICTA-treated subjects experienced weight gain of ≥ 7%. ***Laboratory tests: Serum prolactin:*** increases in serum prolactin observed. ***Class effects:*** QT prolongation, ventricular arrhythmias, sudden unexplained death, cardiac arrest, and Torsade de pointes may occur with antipsychotics. Cases of venous thromboembolism, including pulmonary embolism and deep vein thrombosis, also reported.

Refer to SmPC for other side effects.

PREGNANCY: Should not be used during pregnancy unless clearly necessary.

LACTATION: Should not be used while breastfeeding.

INTERACTIONS: Caution with medicines that prolong QT interval e.g., class IA and class III antiarrhythmics, some antihistaminics, some antibiotics, some other antipsychotics, some antimalarials. ***Potential for TREVICTA to affect other medicines:*** Caution in conjunction with: other centrally acting medicines e.g., anxiolytics, antipsychotics, hypnotics, opiates, alcohol; medicines known to lower seizure threshold i.e., phenothiazines, butyrophenones, tricyclics, SSRI's, tramadol, mefloquine; medicines capable of inducing orthostatic hypotension (an additive effect may be observed when TREVICTA is co-administered); levodopa and other dopamine agonists (paliperidone may antagonize their effect- use lowest effective dose of each treatment if this combination necessary e.g., end-stage Parkinson's disease). Interaction of TREVICTA with lithium unlikely. ***Potential for other medicines to affect***

TREVICTA: Administration of oral paliperidone and paroxetine (a potent CYP2D6 inhibitor) showed no clinically significant effect on paliperidone pharmacokinetics. Co-administration of oral paliperidone once daily with carbamazepine 200 mg twice daily decreases plasma concentration of paliperidone by 37%. Re-evaluate/increase TREVICTA dose at carbamazepine initiation. No clinically significant interaction expected between valproate and TREVICTA. Caution when TREVICTA is co administered with risperidone or with oral paliperidone for extended periods of time. Limited safety data for concomitant use of TREVICTA with other antipsychotics. The combined use of psychostimulants (e.g. methylphenidate) with paliperidone can lead to extrapyramidal symptoms upon change of either/both treatments.

Refer to SmPC for full details of interactions.

LEGAL CATEGORY: Prescription Only Medicine.

PRESENTATIONS, PACK SIZES, MARKETING AUTHORISATION NUMBERS & BASIC NHS COSTS:

PRESENTATION	PACK SIZE	MARKETING AUTHORISATION NUMBER(S)	BASIC NHS COSTS
175 mg pre-filled syringe	1 dose	PLGB 00242/0712	£551.76
		EU/1/14/971/007	
263 mg pre-filled syringe		PLGB 00242/0713	£734.70
		EU/1/14/971/008	
350 mg pre-filled syringe		PLGB 00242/0714	£942.21
		EU/1/14/971/009	
525 mg pre-filled syringe		PLGB 00242/0715	£1177.77
		EU/1/14/971/010	

MARKETING AUTHORISATION HOLDER:
Great-Britain (PLGB): Janssen-Cilag Limited, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG UK.

Northern Ireland (EU); Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Belgium

FURTHER INFORMATION IS AVAILABLE FROM: Janssen-Cilag Limited, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG UK.

Prescribing information last revised: August 2023

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Janssen-Cilag Limited on 01494 567447 or at dsafety@its.jnj.com.

BYANNLI® 700 mg, 1000 mg prolonged-release suspension for injection in pre-filled syringe PRESCRIBING INFORMATION

ACTIVE INGREDIENT(S): 700 mg, 1000 mg paliperidone

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

INDICATION(S): BYANNLI, a 6-monthly injection, is indicated for the maintenance treatment of schizophrenia in adult patients who are clinically stable on 1-monthly or 3-monthly paliperidone palmitate injectable products

DOSAGE & ADMINISTRATION: Gluteal intramuscular injection only. It should be injected slowly, deep into the upper-outer quadrant of the gluteal muscle. Patients who are adequately treated with 1-monthly paliperidone palmitate injection at doses of 100 mg or 150 mg (preferably for four months or more) or 3monthly paliperidone palmitate injection at doses of 350 mg or 525 mg (for at least one injection cycle) and do not require dose adjustment may be transitioned to 6-monthly paliperidone palmitate injection **Adults:** Administer dose in gluteal muscle only. Use 1½ inch, 20 gauge (0.9 mm × 38 mm) needle, regardless of body weight. *BYANNLI for patients adequately treated with 1-monthly paliperidone palmitate at doses of* 100 mg or 150 mg*:* Initiate BYANNLI in place of the next scheduled dose of 1-monthly paliperidone palmitate injectable (± 7 days). The BYANNLI dose should be based on the previous 1-monthly paliperidone palmitate injectable dose. Thereafter BYANNLI should be administered by gluteal intramuscular injection once every 6 months (± 14 days). *BYANNLI for patients adequately treated with 3monthly paliperidone palmitate injection at doses of 350 mg or 525 mg: BYANNLI should be initiated in place of the next scheduled dose of 3-monthly paliperidone palmitate injection (± 14 days).* The BYANNLI dose should be based on the previous 3-monthly paliperidone palmitate injectable dose. Thereafter BYANNLI should be administered by gluteal intramuscular injection once every 6 months (± 14 days). Refer to the SmPC for full details of transitioning patients to BYANNLI. Dose adjustment of BYANNLI can be made every 6 months between the dose levels of 700 mg and 1000 mg. Alternate injections between left and right sides. **Children:** No safety or efficacy data available. **Elderly:** No safety or efficacy data available for patients > 65 years. **Renal impairment:** ***Mild*** (creatinine clearance ≥ 50 to < 80 ml/min): patients stabilised on either 100 mg 1-monthly paliperidone palmitate injectable or 350 mg 3-monthly paliperidone palmitate injectable can be transitioned to BYANNLI at the 700 mg dose only. 1000 mg dose of BYANNLI is not recommended for patients with mild renal impairment. ***Moderate or severe*** (creatinine clearance < 50 ml/min): Not recommended. **Hepatic impairment:** Caution in severe hepatic impairment.

CONTRAINDICATIONS: Hypersensitivity to paliperidone, risperidone or any of the excipients.

SPECIAL WARNINGS & PRECAUTIONS: Do not use in acutely agitated or severely psychotic patients. Not recommended in elderly dementia patients. Caution in cardiovascular disease (including family history of QT prolongation), cerebrovascular disease, hypotension, prolactin-dependent tumours, seizures, Parkinson's disease and in conjunction with medicines that prolong QT interval. May induce orthostatic hypotension. If tardive dyskinesia occurs, consider discontinuing all antipsychotics. Caution is warranted in patients receiving both, psychostimulants (e.g., methylphenidate) and paliperidone concomitantly, as extrapyramidal symptoms could emerge when adjusting one or both medications. Gradual withdrawal of stimulant

treatment is recommended. Events of leucopenia, neutropenia, and agranulocytosis reported with antipsychotics, including BYANNLI, additional monitoring or cessation of treatment may be required. If Neuroleptic Malignant Syndrome (NMS) occurs discontinue all antipsychotics. Rarely, anaphylactic reactions reported in patients previously tolerating oral risperidone/paliperidone. If occur, discontinue BYANNLI, initiate general supportive measures, monitor until resolved. Appropriate clinical monitoring in diabetics and those with risk factors for diabetes advisable. Advise of potential for weight gain, monitor weight regularly. Priapism reported with oral paliperidone. Caution in patients experiencing conditions which may contribute to core body temperature elevation. Identify all possible risk factors for venous thromboembolism (VTE) before and during treatment and take preventive measures. Antiemetic effect (observed in paliperidone preclinical studies) may mask overdosage with certain medicines, intestinal obstruction, Reye's syndrome, brain tumour etc. Avoid inadvertent injection into a blood vessel. Intraoperative floppy iris syndrome (IFIS) observed during cataract surgery in patients treated with medicines with alpha 1aadrenergic antagonist effect, such as BYANNLI.

SIDE EFFECTS: Very Common: insomnia. **Common:** upper respiratory tract infection, urinary tract infection, influenza, hyperprolactinaemia, hyperglycaemia, weight increased, weight decreased, decreased appetite, agitation, depression, anxiety, parkinsonism, akathisia, sedation/ somnolence, dystonia, dizziness, dyskinesia, tremor, headache, tachycardia, hypertension, cough, nasal congestion, abdominal pain, vomiting, nausea, constipation, diarrhoea, dyspepsia, toothache, transaminases increased, musculoskeletal pain, back pain, arthralgia, amenorrhoea, pyrexia, asthenia, fatigue, injection site reaction. **Other side effects reported with paliperidone include:** pneumonia, respiratory tract infection, cellulitis, thrombocytopenia, diabetes mellitus, electrocardiogram QT prolonged, bradycardia, subcutaneous abscess, neutropenia, inappropriate antidiuretic hormone secretion, diabetic ketoacidosis, NMS, cerebral ischaemia, unresponsive to stimuli, loss of consciousness, depressed level of consciousness, glaucoma, atrial fibrillation, pulmonary congestion, pancreatitis, faecaloma, urinary retention, hypothermia, agranulocytosis, anaphylactic reaction, water intoxication, diabetic coma, pulmonary embolism, pneumonia aspiration, intestinal obstruction, ileus, Stevens-Johnson syndrome/toxic epidermal necrolysis, angioedema, rhabdomyolysis, injection site necrosis. **Other side effects reported with risperidone (paliperidone is the active metabolite of risperidone):** ***Weight gain:*** 10.6% of BYANNLI-treated subjects experienced weight gain of ≥ 7%. ***Laboratory tests: Serum prolactin:*** increases in serum prolactin observed. ***Class effects:*** QT prolongation, ventricular arrhythmias, sudden unexplained death, cardiac arrest, and Torsade de pointes may occur with antipsychotics. Cases of venous thromboembolism, including pulmonary embolism and deep vein thrombosis, also reported.

Refer to SmPC for other side effects.

PREGNANCY: Plasma exposure to paliperidone after a single dose of BYANNLI is expected to remain for up to 4 years. BYANNLI should only be used in women planning to become pregnant if clearly necessary. BYANNLI should not be used during pregnancy unless clearly necessary.

LACTATION: Breast-fed infants may be at risk even from BYANNLI administration long before breast-feeding. Patients currently under treatment or who have been treated in the past 4 years with BYANNLI should not breast feed.

INTERACTIONS: Caution with medicines that prolong QT interval e.g., class IA and class III antiarrhythmics, some antihistaminics, some antibiotics, some other antipsychotics, some antimalarials. ***Potential for BYANNLI to affect other medicines:*** Caution in conjunction with: other centrally acting medicines e.g., anxiolytics, antipsychotics, hypnotics, opiates, alcohol; medicines known to lower seizure threshold i.e., phenothiazines, butyrophenones, tricyclics, SSRI's, tramadol, mefloquine; medicines capable of inducing orthostatic hypotension (an additive effect may be observed when BYANNLI is co-administered); levodopa and other dopamine agonists (paliperidone may antagonize their effect- use lowest effective dose of each treatment if this combination necessary e.g., end-stage Parkinson's disease). Interaction of BYANNLI with lithium unlikely. ***Potential for other medicines to affect BYANNLI:*** Administration of oral paliperidone and paroxetine (a potent CYP2D6 inhibitor) showed no clinically significant effect on paliperidone pharmacokinetics. Co-administration of oral paliperidone once daily with carbamazepine 200 mg twice daily decreases plasma concentration of paliperidone by 37%. Reevaluate/increase BYANNLI dose at carbamazepine initiation. No clinically significant interaction expected between valproate and BYANNLI. Caution when BYANNLI is co administered with risperidone or with oral paliperidone for extended periods of time. Limited safety data for concomitant use of BYANNLI with other antipsychotics. The combined use of psychostimulants (e.g. methylphenidate) with paliperidone can lead to extrapyramidal symptoms upon change of either/both treatments

Refer to SmPC for full details of interactions.

LEGAL CATEGORY: Prescription Only Medicine

PRESENTATIONS, PACK SIZES, MARKETING AUTHORISATION NUMBER(S) & BASIC NHS COSTS

PRESENTATIONS	PACK SIZE	MARKETING AUTHORISATION NUMBER(S)	BASIC NHS COSTS
700 mg prolonged-release suspension for injection in pre-filled syringe	1 dose	PLGB 00242/0727 EU/1/20/1453/007	£1,884.42
1000 mg prolonged-release suspension for injection in pre-filled syringe	1 dose	PLGB 00242/0728 EU/1/20/1453/008	£2,355.54

MARKETING AUTHORISATION HOLDER:
Great Britain: Janssen-Cilag Limited, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.
Northern Ireland: Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Belgium.

FURTHER INFORMATION IS AVAILABLE FROM: Janssen-Cilag Limited, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.

Prescribing information last revised: March 2022

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