NEXPOVIO®

selinexor 20mg tablets

ORDERING

NEXPOVIO®

selinexor 20 mg tablets

Introducing XPO1 inhibition: A unique mechanism of action for the treatment of relapsed/refractory multiple myeloma[1–3]

INDICATIONS

NEXPOVIO® (selinexor) is indicated:[2]

- in combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy
- in combination with dexamethasone for the treatment of multiple myeloma in adult patients who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, two immunomodulatory agents and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy

The SmPC-recommended starting dose is 100 mg.[2]

NEXPOVIO® tablets can be ordered using the following PIP codes:

NEXPOVIO® once-weekly dose (4-week pack)	PIP code	Trade price (£)
40 mg (8 x 20 mg tablets)	**5401989**	3,680
60 mg (12 x 20 mg tablets)	**5402003**	5,520
80 mg (16 x 20 mg tablets)	**5402011**	7,360
100 mg (20 x 20 mg tablets)	**5401997**	9,200

Available from AAH Pharmaceuticals. Order via your usual electronic order management system (preferred) or Customer Care on 0344 561 8899.

PIP, Pharmacy Interface Product; SmPC, Summary of Product Characteristics; XPO1, exportin 1.

References

1. Kashyap T, *et al. Oncotarget*. 2016;7(48):78883–78895; 2. NEXPOVIO® (selinexor). Summary of Product Characteristics. Menarini Stemline UK. 2024; 3. Sellin M, *et al. Transl Oncol.* 2022;22:101448.

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 Menarini Stemline via e-mail (adverseevents@menarinistemline.com) or telephone toll-free on +44(0) 800-047-8675.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events.

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Prescribing information is available on the next page.

NEXPOVIO ▼ (selinexor) abbreviated Prescribing Information

Name of the medicinal product: NEXPOVIO 20 mg film-coated tablets **Qualitative and quantitative composition:** Each film-coated tablet contains 20 mg of NEXPOVIO. **Therapeutic indications:** NEXPOVIO is indicated in combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. NEXPOVIO is indicated in combination with dexamethasone for the treatment of multiple myeloma in adult patients who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, two immunomodulatory agents and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy. **Posology and method of administration:** Treatment should be initiated and monitored by a physician experienced in the treatment of multiple myeloma. *Posology Adults NEXPOVIO in combination with bortezomib and dexamethasone (SVd)* The recommended doses based on a 35-day cycle are: NEXPOVIO 100 mg taken orally once weekly on Day 1 of each week; each dose of NEXPOVIO should not exceed 70 mg/m^2. Bortezomib 1.3 mg/m^2 administered subcutaneously once weekly on Day 1 of each week for 4 weeks followed by 1 week off. Dexamethasone 20 mg taken orally twice weekly on Days 1 and 2 of each week. *NEXPOVIO in combination with dexamethasone (Sd)* The recommended doses based on a 4 week cycle are: NEXPOVIO 80 mg taken orally on Days 1 and 3 of each week; each dose of NEXPOVIO should not exceed 70 mg/m^2. Dexamethasone 20 mg taken orally on Days 1 and 3 of each week. See section 4.2 of the Summary of Product Characteristics (SmPC) for full information on dose modification. *Special populations Elderly (≥ 65 years)* No dose adjustment is required for patients over 65 years of age. *Renal impairment* No dose adjustment is required for patients with mild, moderate, or severe renal impairment. There are no data in patients with end-stage renal disease or haemodialysis. *Hepatic impairment* No dose adjustment of NEXPOVIO is required for patients with mild hepatic impairment. There are insufficient data in patients with moderate or severe hepatic impairment to support a dose recommendation. *Paediatric population* The safety and efficacy of NEXPOVIO in children below the age of 18 years of age have not been established. *Method of administration* NEXPOVIO is for oral use and should be taken at approximately the same time during the day. The tablet should be swallowed whole with water. Tablets should not be crushed, chewed, broken, or divided. It may be taken with or without food. For administration of medicinal products administered with NEXPOVIO, refer to their respective SmPC. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 of the SmPC. **Special warnings and precautions for use:** For full information and recommendations on management, please see SmPC section 4.4. For medicinal products administered in combination with NEXPOVIO, consult the relevant SmPC, before prescribing. *Recommended concomitant treatments* Patients should be advised to maintain adequate fluid and caloric intake. Intravenous hydration should be considered for patients at risk of dehydration. Prophylactic concomitant treatment with a 5-HT3 antagonist and/or other antinausea agents should be provided prior to and during treatment. *Haematology* Complete blood counts should be assessed at baseline, and during treatment. Monitor more frequently during the first two months. *Thrombocytopenia* Thrombocytopenia was frequently reported and can be severe (Grade 3/4). In rare cases, potentially fatal haemorrhage can occur. *Neutropenia* Neutropenia including severe neutropenia (Grade 3/4) has been reported. In a few cases, concurrent infections occurred in patients with Grade 3/4 neutropenia. *Gastrointestinal toxicity* Nausea, vomiting, and diarrhoea sometimes can be severe and require the use of antiemetic and antidiarrhoeal medication. See *Recommended concomitant treatments*, above, for prophylaxis. Nausea, vomiting, and diarrhoea can be managed by dose interruptions, modifications, and/or medication. Refer to Tables 1 and 2 in SmPC section 4.2 for dose modifications. *Weight loss and anorexia* NEXPOVIO can cause weight loss and anorexia. Body weight, nutritional status and volume should be checked at baseline and during treatment. Monitoring should be more frequent during the first two months. New or worsening decreased appetite and weight may require intervention and dose modification. Refer to Tables 1 and 2 in SmPC section 4.2 for dose modifications. *Confusional state and dizziness* NEXPOVIO can cause confusional state and dizziness. Patients should avoid situations where symptoms may be a problem and not take other medicinal products that may exacerbate symptoms without medical advice. Patients should not drive or operate heavy machinery until symptoms resolve. *Hyponatraemia* NEXPOVIO can cause hyponatraemia. Sodium levels should be checked at baseline and during treatment. Monitoring should be more frequent during the first two months. Refer to Tables 1 and 2 in SmPC section 4.2 for dose modifications. *Cataract* NEXPOVIO can cause new onset or exacerbation of cataract. Ophthalmologic evaluation may be performed as clinically indicated. *Tumour lysis syndrome* Tumour lysis syndrome (TLS) has been reported. Patients at a high risk for TLS should be monitored closely. *Women of childbearing potential/contraception in males and females* Women of childbearing potential should avoid becoming pregnant during treatment with NEXPOVIO and for at least 1 week following the last dose of NEXPOVIO. Women of childbearing potential and male patients of reproductive potential should be advised to use effective contraception or abstain from sexual activity to prevent pregnancy during treatment with NEXPOVIO and for at least 1 week following the last dose of NEXPOVIO (see SmPC section 4.6). **Undesirable effects (summary only, see SmPC for full details):** *The following undesirable effects are very common (≥1/10):* Pneumonia*, upper respiratory tract infection, bronchitis, nasopharyngitis, thrombocytopenia, anaemia, neutropenia*, leukopenia, lymphopenia, hyponatraemia, dehydration, decreased appetite, hyperglycaemia, hypokalaemia, confusional state, decreased appetite, insomnia, peripheral neuropathy, dizziness, dysgeusia, headache, cataract, vision blurred*, dyspnoea, epistaxis, cough, nausea, diarrhoea, vomiting, abdominal pain, constipation, fatigue, pyrexia, asthenia, weight decreased. *The following undesirable effects are common (≥1/100, < 1/10):* Sepsis*, bacteraemia, Febrile neutropenia, lower respiratory tract infection, leukopenia, lymphopenia, hyponatraemia, dehydration, hypokalaemia, hypocalcaemia, hypophosphataemia, hyperkalaemia, hypomagnesaemia, hyperamylasaemia, hyperuricaemia, hyperlipasaemia, delirium, hallucination, Peripheral neuropathy, confusional state, syncope, amnesia*, cognitive disorder, disturbance in attention, memory impairment, Cataract, visual impairment, balance disorder, dysgeusia, ageusia, taste disorder, vertigo, tachycardia, hypotension, dyspnoea*, epistaxis, abdominal pain, abdominal discomfort, dyspepsia, dry mouth, flatulence, alopecia, night sweats*, pruritus, Muscle spasms, hypercreatinaemia, acute kidney injury, general physical health deterioration, malaise, gait disturbance, chills, aspartate aminotransferase increased, alanine aminotransferase increased, blood alkaline phosphatase increased, fall, contusion. *Includes related terms. *Serious adverse reactions:* The most common serious adverse reactions were pneumonia, cataract, sepsis, diarrhoea, vomiting, thrombocytopenia, anaemia and acute kidney injury. For full information on adverse reactions associated with NEXPOVIO, see SmPC section 4.8. **Legal classification:** POM (Prescription Only Medicine). **Marketing authorisation number:** PLGB 53425/0002 (Great Britain); EU/1/21/1537/001 – EU/1/21/1537/005 (Northern Ireland). **Marketing authorisation holder:** Stemline Therapeutics B.V., Basisweg 10, 1043 AP Amsterdam, Netherlands. **Cost (excluding VAT):** 8 x 20 mg tablets, £3,680; 12 x 20 mg tablets, £5,520; 16 x 20 mg tablets, £7,360; 20 x 20mg tablets, £9,200. **Date of text:** May 2024 (MAT-GB-SEL-00113)

Adverse Event Reporting

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