Maklumat tambahan indikasi
Year 2018
Products Approved For Additional Indication (DCA 321 – 28 Februari 2018)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **Giotrif 20mg film-coated tablets** [Afatinib Dimaleate 20mg] 1.2 **Giotrif 30mg film-coated tablets** [Afatinib Dimaleate 30mg] 1.3 **Giotrif 40mg film-coated tablets** [Afatinib Dimaleate 40mg] 1.4 **Giotrif 50mg film-coated tablets** [Afatinib Dimaleate 50mg]	➢ Indication: *Giotrif as monotherapy is indicated for the treatment of locally advanced or metastatic NSCLC of squamous histology progressing on or after platinum-based chemotherapy.* ➢ Posology: *The recommended dose is 40 mg once daily.* *This medicinal product should be taken without food. Food should not be consumed for at least 3 hours before and at least 1 hour after taking this medicinal product.* *Giotrif treatment should be continued until disease progression or until no longer tolerated by the patient.* *Dose escalation* *A dose escalation to a maximum of 50 mg/day may be considered in patients who tolerate a 40 mg/day starting dose (i.e. absence of diarrhoea, skin rash, stomatitis, and other adverse reactions with CTCAE Grade > 1) in the first cycle of treatment (21 days for EGFR mutation positive NSCLC and 28 days for squamous NSCLC). The dose should not be escalated in any patients with a prior dose reduction. Dose escalation in EGFR TKI pre-treated patients is not recommended. The maximum daily dose is 50 mg.*	**BOEHRINGER INGELHEIM (MALAYSIA) SDN. BHD.** Suite 15-5 Level 15, Wisma UOA Damansara II No 6, Jalan Changkat Semantan,Damansara Heights 50490 Kuala Lumpur
2.	2.1 **XGEVA 120MG SOLUTION FOR INJECTION** [Denosumab 70mg/ml]	➢ Indication: *XGEVA is indicated for the prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in patients with bone metastases from solid tumours.* *Treatment of adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical*	**ZUELLIG PHARMA SDN BHD** No 15, Persiaran Pasak Bumi, Sek. U8 Perindustrian Bukit Jelutong 40150 Shah Alam, Selangor

resection is likely to result in severe morbidity.

- Posology:

XGEVA should be administered under the responsibility of a healthcare professional.

Posology
Supplementation of at least 500 mg calcium and 400 IU vitamin D daily is required in all patients, unless hypercalcemia is present.

Dosage
Prevention of skeletal related events in adults with bone metastases from solid tumours
The recommended dose is 120 mg administered as a single subcutaneous injection once every 4 weeks into the thigh, abdomen or upper arm.

Giant cell tumour of bone
The recommended dose of XGEVA for the treatment of giant cell tumour of bone is 120 mg administered as a single subcutaneous injection once every 4 weeks into the thigh, abdomen or upper arm with additional 120 mg doses on days 8 and 15 of treatment of the first month of therapy.

Patients in the phase II study who underwent complete resection of giant cell tumour of bone did receive an additional 6 months of treatment following the surgery as per study protocol.

Patients with giant cell tumour of bone should be evaluated at regular intervals to determine whether they continue to benefit from treatment. In patients whose disease is controlled by XGEVA, the effect of interruption or cessation of treatment has not been evaluated; however limited data in these patients does not indicate a rebound effect upon cessation of treatment.

<u>Patients with renal impairment</u>
No dose adjustment is required in patients with renal impairment

<u>Patients with hepatic impairment</u>

		The safety and efficacy of denosumab have not been studied in patients with hepatic impairment *<u>Elderly patients (age ≥ 65)</u>* *No dose adjustment is required in elderly patients* *<u>Paediatric population</u>* *The safety and efficacy of XGEVA have not been evaluated in paediatric patients (age < 18) other than skeletally mature adolescents with giant cell tumour of bone.* *XGEVA is not recommended in paediatric patients (age < 18) other than skeletally mature adolescents with giant cell tumour of bone. Treatment of skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity: the posology is the same as in adults. Inhibition of RANK/RANK ligand (RANKL) in animal studies has been coupled to inhibition of bone growth and lack of tooth eruption, and these changes were partially reversible upon cessation of RANKL inhibition*	
3.	**3.1 MENACTRA SOLUTION FOR INJECTION** [Each 0.5 ml dose of vaccine contains the following active ingredients of meningococcal capsular polysaccharides which is conjugated to approximately 48 µg of diphtheria toxoid protein: Serogroup A 4 µg Serogroup C 4 µg Serogroup Y 4 µg Serogroup W-135 4 µg]	➢ Indication: *<u>INDICATIONS AND USAGE</u>* *Menactra®, Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine, is indicated for active immunization to prevent invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, Y and W-135. Menactra vaccine is approved for use in individuals 9 months through 55 years of age. Menactra vaccine does not prevent N. meningitidis serogroup B disease.* ➢ Posology: *<u>DOSAGE AND ADMINISTRATION</u>* *<u>Preparation for Administration</u>* *Menactra vaccine is a clear to slightly turbid solution. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If any of these conditions exist, the vaccine should not be administered.*	**SANOFI-AVENTIS (MALAYSIA) SDN. BHD.** Unit TB-18-1, Level 18, Tower B, Plaza 33 No. 1, Jalan Kemajuan, Seksyen 13 46200 Petaling Jaya, Selangor

		Withdraw the 0.5 ml dose of vaccine from the single dose vial using a sterile needle and syringe. *<u>Dose and schedule</u>* *Menactra vaccine is administered as a single 0.5 ml dose by intramuscular injection, preferably in the anterolateral thigh or deltoid region depending on the recipient's age and muscle mass.* *Do not administer this product intravenously, subcutaneously, or intradermally.* *Primary Vaccination:* • *In children 9 through 23 months of age, Menactra vaccine is given as a 2-dose series at least three months apart.* • *Individuals 2 through 55 years old, Menactra vaccine is given as a single dose.* *Booster Vaccination:* • *A single booster dose may be given to individuals 15 through 55 years of age at continued risk for meningococcal disease, if at least 4 years have elapsed since the prior dose.*	