

## Drugs for risk factors for serious diseases (B)

ATC	Products	Active Substances	Therapeutic indications	Authorisation date (EU)	Available treatments	Superiority (only if available treatments = C)	Therapeutic effect	Therapeutic innovation
B01AC	<u>Iscover</u> , ( <u>Plavix</u> )	Clopidogrel	Clopidogrel is indicated for the prevention of atherothrombotic events in: · Patients suffering from myocardial infarction (from a few days until less than 35 days), ischaemic stroke (from 7 days until less than 6 months) or established peripheral arterial disease. · Patients suffering from non-ST segment elevation acute coronary syndrome (unstable angina or non-Q-wave myocardial infarction) in combination with ASA. For further information please refer to section 5.1 Pharmacodynamic properties.	15-lug-98	C	C1	A	B
G03XC	<u>Optruma</u> , ( <u>EVISTA</u> )	Raloxifene Hydrochloride	OPTRUMA is indicated for the prevention of non traumatic vertebral fractures in postmenopausal women at increased risk of osteoporosis. There are no data on extravertebral fractures. When determining the choice of OPTRUMA or estrogen (hormonal replacement	05-ago-98	C	C1	A	B
B01AX	<u>Quixidar</u> , ( <u>Arixtra</u> )	Fondaparinux Sodium	Prevention of Venous Thromboembolic Events (VTE) in patients undergoing major orthopaedic surgery of the lower limbs such as hip fracture, major knee surgery or hip replacement surgery	21-mar-02	C	C2	A	Pharm
C09CA	<u>Karvea</u> , ( <u>Aprovel</u> )	Irbesartan	Treatment of essential hypertension. Treatment of renal disease in patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive drug regimen (see 5.1 Pharmacodynamic properties).	27-ago-97	C	C2	A	Pharm
C09CA	<u>Micardis</u> , ( <u>Pritor</u> ), [ <u>Telmisartan</u> <u>Boehringer</u> <u>Ingelheim</u> <u>Pharma KG</u> ]	Telmisartan	Treatment of essential hypertension	16/12/1998, (11/12/1998)	C	C2	A	Pharm
C09DA	<u>Coaprovel</u> , ( <u>Karvezide</u> )	Irbesartan/Hydrochlorothiazide	Treatment of essential hypertension. This fixed dose combination is indicated in patients whose blood pressure is not adequately controlled on irbesartan or hydrochlorothiazide alone.	15/10/1998, (16/10/1998)	C	C2	A	Pharm
C09DA	<u>PritorPlus</u> , ( <u>Bolusacplus</u> ) + [ <u>MicardisPlus</u> ]	Telmisartan/Hydrochlorothiazide	Treatment of essential hypertension. PritorPlus fixed dose combination (40mg telmisartan/12.5mg hydrochlorothiazide) is indicated in patients whose blood pressure is not adequately controlled on telmisartan alone.	22/04/2002, (19/04/2002), [19/04/2002]	C	C2	A	Pharm
H05AA	<u>Forsteo</u>	Teriparatide*	Treatment of established osteoporosis in postmenopausal women. A significant reduction in the incidence of vertebral, but not hip fractures has been demonstrated	10-giu-2003	C	C2	A	Pharm
V03AF	<u>Fasturtec</u>	Rasburicase***	Treatment and prophylaxis of acute hyperuricaemia, in order to prevent acute renal failure, in patients with haematological malignancy with a high tumor burden and at risk of a rapid tumor lysis or shrinkage at initiation of chemotherapy	23-feb-01	C	C2	A	Pharm

ATC	Products	Active Substances	Therapeutic indications	Authorisation date (EU)	Available treatments	Superiority (only if available treatments = C)	Therapeutic effect	Therapeutic innovation
A08AB	<u>Xenical</u>	Orlistat	XENICAL is indicated in conjunction with a mildly hypocaloric diet for the treatment of obese patients with a body mass index (BMI) greater or equal to 30 kg/m <sup>2</sup> , or overweight patients (BMI > 28 kg/m <sup>2</sup> ) with associated risk factors. Treatment with orlistat should only be started if diet alone has previously produced a weight loss of at least 2.5 kg over a period of 4 consecutive weeks. Treatment with orlistat should be discontinued after 12 weeks if patients have been unable to lose at least 5% of the body weight as measured at the start of drug therapy.	29-lug-98	C	C2	B	Pharm
B01AC	<u>Integrilin</u>	Eptifibatide	Integrilin is intended for use with acetylsalicylic acid and unfractionated heparin. Integrilin is indicated for the prevention of early myocardial infarction in patients presenting with unstable angina or non-Q-wave myocardial infarction with the last episode of chest pain occurring within 24 hours and with ECG changes and/or elevated cardiac enzymes. Patients most likely to benefit from Integrilin treatment are those at high risk of developing myocardial infarction within the first 3-4 days after onset of acute angina symptoms including for instance those that are likely to undergo an early PTCA (see 5.1).	01-lug-99	C	C2	B	Pharm

\* Biotechnological developed drugs (SEE ANNEX PART "A" - EEC 2309/93)

\*\* Drugs approved in special circumstances