

ANNEX A

| <u>EMA Number</u> | <u>(Invented) name</u> | <u>Strength</u> | <u>Pharmaceutical Form</u> | <u>Route of Administration</u> | <u>Immediate Packaging</u> | <u>Pack size</u> |
|--------------------------|-------------------------------|------------------------|-----------------------------------|---------------------------------------|-----------------------------------|-------------------------|
| EU/1/13/893/001 | Opsumit | 10 mg | Film-coated tablet | Oral use | blister (PVC/PE/PVdC/Alu) | 15 tablets |
| EU/1/13/893/002 | Opsumit | 10 mg | Film-coated tablet | Oral use | blister (PVC/PE/PVdC/Alu) | 30 tablets |
| EU/1/13/893/003 | Opsumit | 10 mg | Film-coated tablet | Oral use | Bottle (HDPE) | 30 tablets |