



Elan  
Drug  
Technologies

## Product Availability List 2009

## Elan Drug Technologies' Product Availability List

Elan Drug Technologies has a number of products available for licensing to pharmaceutical companies in the U.S. and worldwide. These products have incorporated one or more of our drug delivery technologies and are at late stage development or approved for marketing.

Other products at earlier stage development are also available for licensing.

If you are interested in discussing any of these product opportunities in more detail or wish to obtain more information under confidentiality or wish to discuss in-licensing opportunities in general, please contact us:

USA Scott Jenkins – [Scott.Jenkins@elan.com](mailto:Scott.Jenkins@elan.com)  
ROW Sarah Carty – [Sarah.Carty@elan.com](mailto:Sarah.Carty@elan.com)

## Diltiazem Twice Daily (Cardizem<sup>®</sup> SR)

Class/Indication	Calcium antagonist/Anti-hypertensive/anti-anginal.
Dosage Frequency	Twice Daily.
Dosage Form	Multiparticulate SODAS <sup>®</sup> beads in hard gelatin capsules.
Dosage Strength	60mg, 90mg, 120mg, 180mg.
Therapeutic Advantage	<p>Diltiazem (previously marketed as CARDIZEM<sup>®</sup> SR in the U.S.) is a twice daily dosage form of diltiazem developed by Elan Drug Technologies using its microspheroidal SODAS<sup>®</sup> delivery system.</p> <p>Diltiazem's excellent controlled pharmacokinetic and clinical profile allows for its successful use as an antihypertensive agent in addition to its proven antianginal qualities.</p>
Licensing Status	<p>Launched in US and some European and Asia markets.</p> <p>Available for licensing in number of European territories.</p>

## Diltiazem Once Daily (Cardizem® CD)

Class/Indication	Calcium antagonist/Anti-hypertensive/anti-anginal.
Dosage Frequency	Once Daily.
Dosage Form	Multiparticulate SODAS® beads in hard gelatin capsules.
Dosage Strength	90 mg, 120 mg, 180 mg, 240 mg.
Therapeutic Advantage	<p>This once daily form of Diltiazem was developed by Elan Drug Technologies to provide the hypertensive patient with a highly controlled and effective method of managing blood pressure while offering the angina suffered with a more convenient medication.</p> <p>The sophisticated delivery and the wide range of dosage strengths allow for easy titration and adjustment to suit the patient's individual needs.</p>
Licensing Status	<p>Launched in US and some European and Asia markets.</p> <p>Available for licensing in number of European territories.</p>

## Docetaxel Solvent Free Formulation

Class/Indication	Taxanes/Solid Tumour cancers.
Dosage Form	Lyphophilised, nanoparticulate IV formulation of Docetaxel.
Dosage Strength	Preclinical dose ranging studies performed.
Comment	<p>Unlike Taxotere<sup>®</sup>, Elan Drug Technologies' NanoCrystal<sup>®</sup> formulation does not require solvents such as polysorbate 80 and ethanol to solubilise the drug.</p> <p>The NanoCrystal<sup>®</sup> formulation contains sterilised water and GRAS stabilisers and is devoid of solvents.</p> <p>Elan Drug Technologies is seeking a licensing partner that has development and marketing expertise in oncology to develop and market this unique formulation of docetaxel.</p>
Licensing Status	<p>Clinical development.</p> <p>Available for licensing all territories.</p>

## Megesterol acetate

Class/Indication	Progestins/Cachexia.
Dosage Frequency	5ml.
Dosage Form	Oral suspension using the NanoCrystal <sup>®</sup> technology.
Dosage Strength	625mg/5ml.
Therapeutic Advantage	<p>Through applying the NanoCrystal<sup>®</sup> technology, a superior more palatable product with a significantly lower dosage than original product was developed.</p> <p>Viscosity reduced 16-fold, volume swallowed reduced by 75% and has a free of food effect.</p> <p>Indicated for treatment of anorexia, cachexia or unexplained significant weight loss in patients with AIDS.</p>
Licensing Status	<p>Approved and launched in the US in 2005 as Megace<sup>®</sup> ES.</p> <p>Available for licensing in all territories ex-US.</p>

## Morphine Once Daily (Avinza<sup>®</sup>, Morphelan<sup>®</sup>)

Class/indication	Narcotic analgesic/Severe chronic pain.
Dosage Frequency	Once daily.
Dosage Form	Multiparticulate SODAS <sup>®</sup> beads in hard gelatin capsules.
Dosage Strength	30mg, 60mg, 90mg and 120mg.
Comment	<p>Elan Drug Technologies has received approval with the FDA and is marketing through a licensing partner in the U.S. their once daily oral morphine product which gives round the clock pain relief without breakthrough pain.</p> <p>Other once daily formulations, which have been launched, do not provide adequate cover for full 24-hour relief and often have to be supplemented with other analgesics to relieve breakthrough pain - this Elan Drug Technologies formulation overcomes this problem.</p>
Licensing Status	<p>Approved and launched in the US in 2002.</p> <p>Available for licensing in all territories ex-North America.</p>

## Naproxen Sodium (Naprelan<sup>®</sup>)

Class/Indication	Non-steroidal anti-inflammatory/anti-rheumatic, pain relief.
Dosage Frequency	Once daily.
Dosage Form	High-density multiparticulate IPDAS <sup>®</sup> cores in a specialised table matrix
Dosage Strength	500 mg
Comment	<p>Elan Drug Technologies has developed a once daily form of Naproxen for use as anti-rheumatic/arthritis and analgesic.</p> <p>The specialised tablet matrix allows for rapid disintegration and a micro-dispersion of the IPDAS<sup>®</sup> cores in the gastrointestinal tract.</p> <p>The nature of the controlled diffusion and absorption of Naprelan<sup>®</sup> reduces gastrointestinal side effects normally seen with naproxen.</p>
Licensing Status	<p>Launched in the US and Canada.</p> <p>Available for licensing in all territories ex-North America.</p>

## Nifedipine (Afeditab<sup>®</sup>)

Class/Indication	Calcium antagonist/Antihypertensive/antianginal.
Dosage Frequency	Once daily.
Dosage Form	MXDAS <sup>™</sup> tablet.
Dosage Strength	30mg and 60mg.
Comment	<p>Elan Drug Technologies nifedipine is a once daily AB rated version of Bayer's Adalat<sup>®</sup> CC, which is commercially marketed in the US as Afeditab<sup>®</sup>.</p> <p>The product is available in other territories.</p>
Licensing Status	<p>Launched and marketed in the U.S.</p> <p>Available for licensing in all territories ex-U.S.</p>

## Novel Diagnostic Imaging Agents

Class/Indication	Diagnostic imaging agents.
Dosage Form	Nanoparticulate size diagnostic agents using NanoCrystal® formulation
Comment	Elan Drug Technologies' portfolio of novel, NanoCrystal® diagnostic imaging agents have clear advantages over current iodinated contrast agents. A portfolio of patent protected diagnostic agents is available for licensing which have excellent contrast for an extended period of time. EDT's portfolio of NanoCrystal® imaging agents are poorly-water soluble, non-osmotic, iodine-rich compounds. Adjustable hydrolysable linkages allow for a controlled elimination and slow diffusion of the Nano- DI agents which provide significantly longer residence time than current iodinated agents.
Licensing Status	<p>EDT has a portfolio of imaging compounds in pre-clinical development. Lead compounds have been identified, which have been found to be stable.</p> <p>To date, in vivo studies have been completed in rabbits.</p> <p>Available for licensing in all territories worldwide.</p>

## Verapamil (Verelan<sup>®</sup>)

Class/Indication	Calcium antagonist/Antihypertensive/antianginal.
Dosage Frequency	Once daily.
Dosage Form	Multiparticulate SODAS <sup>®</sup> beads in hard gelatin capsules.
Dosage Strength	80 mg, 120 mg, 180 mg, 240 mg and 360mg.
Comment	<p>Verelan<sup>®</sup> is a unique once daily formulation of Verapamil.</p> <p>It is approved for once daily administration up to the maximum total daily dose, whereas other SR products are required to be administered in divided doses.</p> <p>Also, Verelan<sup>®</sup> does not exhibit any food effects and a wide range of dosage options are available, allowing for easy titration for all patients.</p>
Licensing Status	<p>Launched in US, Japan and some European and Asian markets.</p> <p>Available for licensing in number of European territories.</p>

## Verapamil PM (Verelan<sup>®</sup> PM)

Class/Indication	Calcium antagonist/ Antihypertensive/antianginal.
Dosage Frequency	Once daily.
Dosage Form	Multiparticulate CODAS <sup>®</sup> beads in hard gelatin capsules.
Dosage Strength	100mg, 200mg and 300mg.
Comment	<p>Verelan<sup>®</sup> PM is a unique once daily formulation of Verapamil which offers the patient maximum protection against the morning surge in blood pressure when patients are most at risk.</p> <p>The CODAS<sup>®</sup> technology provides peak dose levels in the early morning.</p> <p>Also, Verelan<sup>®</sup> PM does not exhibit any food effects and a wide range of dosage options are available, allowing for easy titration for all patients.</p>
Licensing Status	<p>Launched in the US.</p> <p>Available for licensing all territories ex-US.</p>