

Sweetman S (Ed), Martindale: The complete drug reference. London: Pharmaceutical Press. Electronic version, (2007).

Urea

Sub-sections

- Drug Nomenclature
- Physicochemical Characteristics
- Adverse Effects and Precautions
- Pharmacokinetics
- Uses and Administration
- Preparations

Urea

Drug Nomenclature

Date of monograph revision: 13-Aug-1997; 07-Aug-1998; 11-Jan-2001; 06-Dec-2001; 16-Jun-2004; 17-Jul-2006; (last modified: 25-Nov-2006)

Synonyms: Carbamide; E927b; Karbamid; Močovina; Mocznik; Urea, Karbamidi; Ureia; Uréja; Ureum

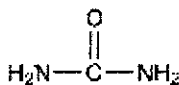
Chemical name: Carbonic acid diamide

Molecular formula: $\text{NH}_2\text{CO.NH}_2 = 60.06$

CAS: 57-13-6


ATC code: B05BC02; D02AE01

Read code: y0CJZ [13C]



Chemical Structure of Urea

NOTE:

Use in Sport. Urea may be restricted in certain sports, see , as it is considered to be a member of a prohibited group (Diuretics); competitors should check with the appropriate sports authorities.

Pharmacopoeias:

In *Chin.*, *Eur.* (see ) , *Jpn.*, *Pol.*, and *US*.

Ph. Eur. 5.5 (Urea). Transparent, slightly hygroscopic, crystals or a white crystalline powder. Very soluble in water; soluble in alcohol; practically insoluble in dichloromethane. Store in airtight containers.


USP 29 (Urea). Colourless or white, practically odourless, prismatic crystals, or white crystalline powder or pellets. May gradually develop a slight odour of ammonia on prolonged standing. Soluble 1 in 1.5 of water, 1 in 10 of alcohol, and 1 in 1 of boiling alcohol; practically insoluble in chloroform and in ether. Solutions are neutral to litmus. Store at a temperature of 25 degrees, excursions permitted between 15 degrees and 30 degrees.

Physicochemical Characteristics

Incompatibility.

Urea can cause haemolysis when mixed with **blood** and should never be added to whole blood for transfusion or given through the same set by which blood is being infused.

Adverse Effects and Precautions

As for Mannitol, .

Urea is reported to be more irritant than mannitol, and intravenous use may cause venous thrombosis or phlebitis at the site of injection; extravasation may cause sloughing or necrosis. Only large veins should be used for infusion, and urea should not be infused into veins of the lower limbs of elderly subjects. Extreme care is essential to prevent accidental extravasation of urea infusions.

Rapid intravenous injection of solutions of urea can cause haemolysis; the risk is reduced by using glucose or invert sugar solutions as diluent. Urea should not be administered with whole blood.

Topical applications may be irritant to sensitive skin.

Infants and neonates.

High plasma-urea concentrations have been reported^{1,2} in neonates after topical application of emollient creams containing urea. Since there was no evidence of dehydration^{2,3} absorption of urea through the skin was the likely cause. Raised plasma-urea concentrations have been reported⁴ in infants with erythematous skin conditions who had not been treated with urea cream and this was attributed to dehydration due to increased insensible water loss through the damaged skin.

1. Beverley DW, Wheeler D. High plasma urea concentrations in collodion babies. *Arch Dis Child* 1986; **61**: 696-8. PubMed
2. Oudesluys-Murphy AM, van Leeuwen M. High plasma urea concentrations in collodion babies. *Arch Dis Child* 1987; **62**: 212.
3. Beverley DW, Wheeler D. High plasma urea concentration in babies with lamellar ichthyosis. *Arch Dis Child* 1986; **61**: 1245-6.
4. Garty BZ. High plasma urea concentration in babies with lamellar ichthyosis. *Arch Dis Child* 1986; **61**: 1245. PubMed

Pregnancy.

There have been reports of women suffering coagulopathy associated with urea given for termination of pregnancy.^{1,2}

1. Grundy MFB, Craven ER. Consumption coagulopathy after intra-amniotic urea. *BMJ* 1976; **2**: 677-8. PubMed
2. Burkman RT, et al. Coagulopathy with midtrimester induced abortion: association with hyperosmolar urea administration. *Am J Obstet Gynecol* 1977; **127**: 533-6. PubMed

Pharmacokinetics

Urea is fairly rapidly absorbed from the gastrointestinal tract but causes gastrointestinal irritation. Urea is distributed into extracellular and intracellular fluids including lymph, bile, CSF, and blood. It is reported to cross the placenta, and penetrate the eye. It is excreted unchanged in the urine.

Uses and Administration

Urea promotes hydration and is mainly applied **topically** in the treatment of ichthyosis and hyperkeratotic skin disorders (☞☒). Used intravenously it has osmotic diuretic properties similar to mannitol (☞☒) and has been used in the treatment of acute increases in intracranial pressure (☞☒), due to cerebral oedema, and to decrease intra-ocular pressure in acute glaucoma (☞☒), but has been largely superseded by mannitol. Urea has also been given intra-amniotically for the termination of pregnancy (☞☒).

When applied topically urea has hydrating and keratolytic properties. In the management of ichthyosis and other dry skin disorders it is applied in creams or lotions containing 5 to 25% urea. A preparation containing 40% may be used for nail destruction.

For the reduction of raised intracranial or intra-ocular pressure, urea is given intravenously, as an infusion of a 30% solution in glucose 5 to 10% or invert sugar 10%, at a rate not exceeding 4 mL/minute, in a dose of 0.5 to 1.5 g/kg to a maximum of 120 g daily. For children under 2 years a dose of 100 mg/kg has been suggested. Rebound increases in intracranial and intra-ocular pressure may occur after about 12 hours.

Solutions of urea 40 to 50% have been given by intra-amniotic injection for the termination of pregnancy.

Urea labelled with carbon-13 (☞☒) is used in the *in vivo* diagnosis of *Helicobacter pylori* infection (see Peptic Ulcer Disease, ☞☒). The test involves collecting a breath sample before and after oral ingestion of a single dose of ¹³C-urea. *H. pylori* produces urease which hydrolyses the urea to carbon dioxide and ammonia; therefore, an excess of carbon-13-labelled carbon dioxide in the sample, compared with a baseline sample, indicates infection. Doses of ¹³C-urea include 50 mg, 75 mg, or 100 mg depending on the kit being used. Urea labelled with the radionuclide carbon-14 is also used in a urea breath test for *H. pylori* detection.

Preparations

Single-ingredient Preparations

The symbol ☒ denotes a preparation which is discontinued or no longer actively marketed.

Argentina: Hidroplus; Keratopic; Lociherp; Nutralcon; Optiwhite; Ureadin; Urecrem; Uremol; Xerobase; **Australia:** Aquacare; Aquadrate☒; Hamilton Dry Skin; Nutraplus; Urecare; Urederm; **Austria:** Basodexan☒; Excipial U☒; Nubral; **Brazil:** Emoderm; Hidrapel; Nutraplus; Ureadin; **Canada:** Aqua Care☒; Dermaflex; Nutraplus☒; Onyvul☒; Rhodurea☒; Ultra Mide; Uree; Uremol; Urisec; Velvelan☒; **Chile:** Ayr con urea; Ayr-5; Hyderm; Nutraplus☒; Uramol; Ureadin 10 and 20; **Czech Republic:** Excipial U; **Finland:** Fenuril; **France:** Anti-Dessechement; Charlieu Topic; Ictyoderm; Nutraplus; Urecrem☒; **Germany:** Balisa; Basodexan; Elacutan; Eucerin Salbe; Hyanit N☒; Laceran☒; Linola Urea; Nubral; Onychomal; Penaderm☒; Rubio N☒; Sebexol cum urea; Ureotop; **Hong Kong:** Balneum Intensiv; Carmol; Euderm; Nutraplus☒; Urecare; Urederm; **Ireland:** Aquadrate; Nutraplus; **Italy:** Dermal Care; **Malaysia:** Balneum Intensiv; Euderm☒; Nutraplus; UO; Urecare☒; **Mexico:** Derma-Keri; Dermoplast; Karmosan; Nutraplus; Uramol; **Netherlands:** Alphadrate☒; **New Zealand:** Aquacare; Nutraplus; **Portugal:** Eucerin Pele Seca; Laceran☒; Rebladerm; Ureadin 10 and 20; **South Africa:** Eulactol☒; Nutraplus☒; **Singapore:** Aqrea; Balneum Intensiv; Euderm☒; Nutraplus; Urecare; **Spain:** Nutraplus; **Sweden:** Calmuril; Canoderm; Caress; Fenuril; Karbaderm☒; Karbasal; Monilen;

Switzerland: Basodexan \square ; Carbamide Emulsion; Eucerin peau seche; Excipial U; Linola Uree; Nutraplus; Vita-Merfen Soins dermatologiques \square ; **Thailand:** Balneum Intensiv \square ; Nutraplus; **Turkey:** Excipial; Nutraplus; Urederm; **United Kingdom:** Aquadrate; Nutraplus; **United States:** Aquacare; Atrac-Tain \square ; Carmol ; Dr Scholl's Smooth Touch Deep Moisturizing Cream \square ; Gormel; Keralac; Lanaphilic; Nutraplus; Ultra Mide; Umecta; Ureacin; Ureaphil; Vanamide; **Venezuela:** Uricrim;

Multi-ingredient Preparations

The symbol \square denotes a preparation which is discontinued or no longer actively marketed.

Argentina: Acilac; Akerat; Aloebel; Cremisona \square ; Cremsor N; Hidrolac; Lactiderm HC \square ; Lactiderm; Lactocrem; Masivol Urea; Onixol \square ; Oxidermos; Sadeltan F; Turgent Colageno; Turgent Emulsion; Urecrem Hidro; **Australia:** Aussie Tan Skin Moisturiser; Calmurid ; Curaderm \square ; Dermadrate; Psor-Asist; SP Cream \square ; **Austria:** Aleot; Calmurid comp \square ; Calmurid HC; Calmurid; Canesten Bifonazol comp; Fungiderm comp \square ; Hydrodexan \square ; Ichth-Oestren; Keratosis forte; Keratosis; Mirfulan; Mykozem \square ; Optiderm; Psoradexan \square ; **Belgium:** Alphaderm \square ; Calmurid ; **Brazil:** Colpanist \square ; Donnagel ; Emoderm \square ; Oticerim; Oto-Biotic ; Sedaucic \square ; Tricolpex; Tricomax ; Vagi Biotic; Vagi-Sulfa; **Canada:** Amino-Cerv; Calmurid \square ; Calmurid HC \square ; Hydrophil; Kerasal; Sential \square ; Ti-U-Lac HC \square ; Ti-U-Lac; Uremol-HC; **Chile:** Akerat; Mycosporan Onycoset \square ; Ureadin Facial; Ureadin Forte; Ureadin Pediatrics; **Czech Republic:** Betacorton U; Mycospor Sada na Nehty; **Denmark:** Mycospor Carbamid \square ; **Finland:** Calmuril; Wicaran; Wicarba; Wicnecarb; Wicnevit; **France:** Akerat; Amycor Onychoset; Charliu Topicrem; Keratosane \square ; Liperol ; Nightpeel; Pedi-Relax Anti-calloites; Provicтол; **Germany:** Balisa VAS; Brand- u. Wundgel-Medice N; Calmurid HC \square ; Calmurid; Carbamid + VAS; Condilan \square ; Dijozol \square ; Fungidexan; Grune Salbe "Schmidt" N \square ; Hydrodexan; Ichth-Oestren \square ; Jacosulfon \square ; Kelofibrase \square ; Mirfulan; Mycospor Nagelset; Nubral 4 HC \square ; Nubral 4; Nubral Forte \square ; Oestrugol N \square ; Optiderm; Prologol-liquid N \square ; Psoradexan; Psorigerb N \square ; Remederm; Sulfokoll \square ; Thrombimed \square ; Ureata S \square ; Ureotop + VAS; **Greece:** Lyoderm \square ; Urecortin; **Hong Kong:** Balneum Intensiv Plus; Dermadrate; **Hungary:** Reseptyl-Urea; Squa-med; **India:** Cotaryl; **Ireland:** Alphaderm; Calmurid ; Calmurid HC; Psoradrate \square ; **Israel:** Agispor Onychoset; Calmurid ; Calmurid HC; Derma-Care ; Keratospo; U-Lactin Foot Cream; U-Lactin Forte; **Italy:** Eudermico; Gel Tar \square ; Hidro Tar 30 \square ; Keraflex; Optiderm; Otocaina \square ; Verunec; Xerial; **Malaysia:** Balneum Intensiv Plus; Ucert ; **Mexico:** Eucerin Piel Seca/Reseca \square ; Hidribet 5; Hidribet; Lowila; Mycospor Onicoset; Ureaderm Lactato; **Netherlands:** Alphacortison \square ; Calmurid ; Calmurid HC; Symbial; **Norway:** Mycospor Carbamid \square ; **New Zealand:** Calmurid \square ; Dermadrate; **Portugal:** Calmurid ; Carmitol; Creme Laser Hidrante; Hidratoderme; Mycospor \square ; Optiderm \square ; U Lactin; Ureadin 10 Plus; Ureadin 30; Ureadin Facial; Ureadin Forte; Ureadin Maos; **Russia:** Mycospor (Микоспор); **South Africa:** Calmurid HC \square ; Covancaine; **Singapore:** Balneum Intensiv Plus; Dermadrate; Topicrem; **Spain:** Ant Sedan \square ; Antisept Sed \square ; Cortisdin Urea; Kanapomada; Mycospor Onicoset; **Sweden:** Calmuril-Hydrokortison \square ; Fenuril-Hydrokortison; Mycosporan Karbamid \square ; **Switzerland:** Acne Gel; Antikeloides Creme; Betacortone; Calmurid ; Calmurid HC \square ; Carbamide + VAS; Carbamide Creme; Kerasal; Klyx Magnum; Optiderm; Psoradexan \square ; Sebo Creme; Sebo-Psor; Tretinoine \square ; Turexan Capilla; Turexan Lotion; Undex \square ; **Thailand:** Balneum Intensiv Plus \square ; Gynestine; **Turkey:** Betacorton; Kerasal; Mycospor; Ureacort; **United Kingdom:** Alphaderm; Antipeol; Balneum Plus; Calmurid HC; Calmurid; Cymex; E45 Itch Relief; Psoradrate \square ; Sential E \square ; Sential HC \square ; St James Balm; Vesagex Heelbalm; **United States:** Accuzyme; Allanfil; AllanZyme; Alphaderm \square ; Amino-Cerv; Dayto Sulf \square ; Ethezyme; Fostex Medicated Cleansing Bar \square ; Gladase-C; Gladase; Hydrocerin Plus; Kovia; Panafil-White; Panafil; Pap-Urea; Rosula NS; Rosula; Ziox; **Venezuela:** Caduril; Hidribet; Mycospor Onicoset; Pantonic; Urimet; Urisalic;

Pharmacopoeial Preparations

BP 2005: Urea Cream; **USP 29:** Urea for Injection;