Brenée,

Since our IHE PCD Pump WG discussion last Wednesday, several of us have focused on precisely identifying the base unit of measure for the proposed UCUM [mgPE] unit, and based on both clinical feedback from pharmacologists and further exploration of more recent FDA reviewed and approved drug labels, we have concluded that **Phenytoin Sodium** should be our reference substance with chemical structure \( \text{C}_{15}\text{H}_{11}\text{N}_{2}\text{NaO}_{2} \) and molecular weight of **274.25 g/mol**. [PubChem CID: 657302]

As a consequence, we would like to revert back to the original proposal captured in UCUM ticket URL [https://ucum.org/trac/ticket/5791](https://ucum.org/trac/ticket/5791) by restoring ‘sodium’ in the suggested entries in UCUM Table 19 in §45 chemical and biochemical units, as shown below.

The suggested entries in Table 19 in §45 chemical and biochemical units are shown below but are certainly open for further discussion.

<table>
<thead>
<tr>
<th>name</th>
<th>milligrams of phenytoin sodium equivalents</th>
</tr>
</thead>
<tbody>
<tr>
<td>kind of quantity</td>
<td>mass equivalent (of a prodrug of phenytoin)</td>
</tr>
<tr>
<td>print</td>
<td>mgPE</td>
</tr>
<tr>
<td>c/s</td>
<td>[mgPE]</td>
</tr>
<tr>
<td>c/I</td>
<td>[MGPE]</td>
</tr>
<tr>
<td>M</td>
<td>no</td>
</tr>
</tbody>
</table>

| definition value | definition unit |

Examples of use:

English: drug strength is “50 mg PE/mL” with the note (PE=phenytoin sodium equivalents)

UCUM: value = 50, units = [mgPE]/mL

English: a single dose of “400 mg PE”

UCUM: value = 400, units = [mgPE]

I also determined that more recent FDA labels/inserts and other literature published on or after 2015 include the less ambiguous statement:

“1 mg PE is equivalent to 1 mg phenytoin sodium”

and I recommend that we use the Pfizer label/insert to **Cerebyx® Fosphenytoin Sodium** Injection as an
CEREBYX® (fosphenytoin sodium injection) is a prodrug intended for parenteral administration; its active metabolite is phenytoin. 1.5 mg of fosphenytoin sodium is equivalent to 1 mg phenytoin sodium, and is referred to as 1 mg phenytoin sodium equivalents (PE). The amount and concentration of fosphenytoin is always expressed in terms of mg PE.

The label has the clarion statement (my highlighting added) on page 6:

DOSES OF CEREBYX ARE ALWAYS EXPRESSED IN TERMS OF MILLIGRAMS OF PHENYTOIN SODIUM EQUIVALENTS (mg PE) 1 MG PE IS EQUIVALENT TO 1 MG PHENYTOIN SODIUM.

I would need additional guidance from you and your colleagues regarding the content of definition value and definition unit. Please do not hesitate to contact me if you or others on the UCUM review committee have any questions or comments.

Thanks and regards,

Paul Schluter, PhD

IHE DEV Rosetta Working Group Chair

e-mail: psschluter@gmail.com

cell: (414) 702-2026

On Nov 10, 2021, at 3:26 PM, Paul Schluter <psschluter@gmail.com> wrote:

Brenée,

Our meeting regarding the proposed UCUM [mgPE] unit-of-measure went very well today. After looking into this over the past several days, Dr. Steven Dain agreed with our approach since ‘mgPE’ is already widely used on drug labels and clinicians and systems already use this as an informal unit. We recommend that you proceed with the UCUM Committee review for this proposal.

We would like to modify the original proposal captured in UCUM ticket URL https://ucum.org/trac/ticket/5791 by removing ‘sodium ’ in the suggested entries in UCUM Table 19 in §45 chemical and biochemical units, as shown below. This will eliminate any confusion regarding the reference substance and molecular weight for Phenytoin = C₁₅H₁₁N₂O₂ and 252.268 g/mol [PubChem CID: 1775].

I would need additional guidance from you and your colleagues regarding the content of definition value and definition unit. Please do not hesitate to contact me if you have any questions or comments.
The suggested entries in Table 19 in §45 chemical and biochemical units are shown below but are certainly open for further discussion.

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Examples of use:

English: drug strength is “50 mg PE/mL” with the note (PE=phenytoin sodium equivalents)
UCUM: value = 50, units = [mgPE]/mL

English: a single dose of “400 mg PE”
UCUM: value = 400, units = [mgPE]

On Nov 10, 2021, at 9:57 AM, Mitchell, Brenée Elise <mitchbre@regenstrief.org> wrote:

Thank you Paul.

I will wait to hear the results of today’s meeting before sending to the UCUM committee for review.

Thanks again,

Brenée Mitchell, MS
Content Developer, LOINC
Regenstrief Institute
1101 West Tenth Street
Indianapolis, IN 46202
Steven,

I have also reviewed the drug label images for fosphenytoin (example attached) and related drugs available on Google and the majority embed the foundational unit-of-measure phase “mg PE”.

The proposed UCUM [mgPE] captures the essential aspects of this unit-of-measure: ‘mg’ (mass) and ‘PE’ (Phenytoin Equivalent) and enclosing them in square brackets […] as a single unit atom. This is clear and unambiguous.

I have not found literature or Google references that use “PGE” units. Could you kindly provide a link?

I welcome comments from everyone else. I have also copied Brenée Mitchell, MS, Content Developer for LOINC, who will be guiding this through the Regenstrief/LOINC/UCUM committee process.

Best regards,

Paul Schluter, PhD

IHE DEV Rosetta Working Group Chair
On Nov 8, 2021, at 5:06 PM, Steven Dain <sdain@rogers.com> wrote:

Hi Paul I was looking at this more closely over the weekend. It looks like the FDA monograph for fosphenytoin uses PGE units.

I'm kind of surprised that they did this. I looked at various packaging appendages from Google images for fosphenytoin, and some of the vials were labelled in PGE units.

So I suppose it would be prudent to use those units within pumps to avoid confusion.

Best regards,

Steven

Please excuse the typos

On Mon, Nov 8, 2021 at 17:56, Paul Schluter <psschluter@gmail.com> wrote:

Kurt, Lisa, Steven and colleagues,

I am sending you the ‘Extra Meeting’ Zoom invitation that Sarah sent earlier this afternoon with a clear linkage to the [mgPE] discussion, now scheduled for 3:00 PM EST on Wednesday, November 10. Please feel free to forward this invitation to others.

In an earlier private email Dr. Steven Dain, MD, indicated that he had concerns about the proposed “[mgPE] UCUM unit-of-measure for “milligrams of Phenytoin Equivalents”.

The UCUM ticket URL is https://ucum.org/trac/ticket/5791 and will be formally reviewed by the UCUM review group associated with LOINC and Regenstrief within the next few weeks.
I believe that this topic should be further discussed by the IHE DEV/PCD Pump WG and other experts. Steven is available for this discussion on Wednesday at 3:00 PM EST and most of the attendees at the IHE PCD Pump WG meeting today thought this would be the best time from the choices available to us.

In the meantime, if there is any material that anyone would like to share about the proposed [mgPE] unit-of-measure, please feel free to send it to the group above; otherwise, we will consider everyone’s thoughts and concerns during the call.

Thanks to Sarah and Kurt for setting up the Zoom meeting, and best regards,

Paul Schluter, PhD

IHE DEV Rosetta Working Group Chair

email: psschluter@gmail.com
cell: (414) 702-2026

On Nov 8, 2021, at 2:12 PM, IHE International <ihe_Intl@himss.org> wrote:

**Additional meeting for PCD Pump Workgroup.**

IHE International Coordinator is inviting you to a scheduled Zoom meeting.

**Join Zoom Meeting**
https://himss.zoom.us/j/92241767931?pwd=TEtqSUVMakExdHhpRUNZVnJXSWxrQT09

Meeting ID: 922 4176 7931
Passcode: 155898
One tap mobile
+16699006833,,92241767931# US (San Jose)
+13462487799,,92241767931# US (Houston)
Dial by your location
+1 669 900 6833 US (San Jose)
+1 346 248 7799 US (Houston)
+1 253 215 8782 US (Tacoma)
+1 301 715 8592 US (Washington DC)
+1 312 626 6799 US (Chicago)
+1 929 205 6099 US (New York)
833 548 0282 US Toll-free
877 853 5257 US Toll-free
888 475 4499 US Toll-free
833 548 0276 US Toll-free
Meeting ID: 922 4176 7931
Find your local number:
https://himss.zoom.us/u/azAA1GxKz